

EPA Reg. No. 1381-170
Vol. 3



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

May 18, 2005

MEMORANDUM:

Subject: ACTELIC 5E INSECTICIDE
EPA Reg. No.: 1381-170
SLN: WA900038
Re: PRB Preliminary Label assessment

From: Judy Loranger *Judy Loranger 5/18/05*
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

Through Lawrence Schnaubelt *Lawrence Schnaubelt 5/17/05*
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

To: Meredith Laws, Chief
Insecticide-Rodenticide Branch
Registration Division (7505C)

BACKGROUND: Agrilience, LLC has submitted 5 copies of draft labeling for the subject parent product and the SLN (WA900038) in its 8 month response to the Pirimiphos-methyl IRED. PRB has completed a preliminary assessment of the draft labeling. In its assessment, PRB has considered the following: 1) Labeling requirements specified in the Pirimiphos-methyl IRED; 2) Labeling specified or required in the Product Chemistry and Acute Toxicity Reviews for the subject product; and 3) Labeling requirements as specified in 40 CFR Part 156.10 and associated labeling policy documents such as the Label Review Manual or Pesticide Regulation Notices (PRNs). In addition, PRB has included recommendations to improve the comprehension and consistency of all product labels. A copy of this assessment may be accessed electronically on the Lan through the Q:Drive in Word Perfect. The path is q:\prb\label\001381\170.

NOTE: This preliminary assessment contains recommendations intended to assist Product Managers in their final review of the pesticide label. Product Managers are encouraged to use all or portions of this assessment and then apply their own knowledge of the subject product and the product's regulatory history (including comparison with existing stamped accepted labeling) to conduct a final review of the label. It is the responsibility of the PM to attain the necessary label improvements required for an amended product reregistration (final product reregistration cannot occur until the Agency completes its cumulative risk assessment of the organophosphate pesticides).

SUMMARY OF FINDINGS:

I RED Risk Mitigation:

The subject product label (parent product only) contain risk mitigation labeling requirements as specified in the IRED. (SLN labeling issues are addressed below in Section IV.)

II Technical Review Requirements:

The subject product label does not contain the required labeling as specified in the acute toxicity review signed 2/10/03.

As per the acute toxicity review:

- This product meets the criterion for restricted use classification based on data that place it in Toxicity Category I for eye irritation.
- Revisions are needed to the signal word section.
- Revisions are needed to the First Aid statements.
- PRB recommends additional text be added to the Note to Physician.
- The Hazards to Humans and Domestic Animals statements must be revised.

Refer to Appendix I for more details.

No label revisions are needed per the product chemistry review.

III Other Labeling Requirements:

The subject product does not contain the required labeling as specified by 40 CFR Part 156.10, PR Notices and the Label Review Manual.

- PRB recommends that the company's phone number be placed on the label.
- The registrant should correct the typographical error on the top of Page 5.
- The warranty section needs revision.

Refer to Appendix I for more details.

IV SLN

SLN WA900038 allows use on iris bulbs in Washington state. Appendix I-A of this assessment addresses the label deficiencies found on the SLN label that include:

- The registrant for this SLN registration is a third party, Washington Bulb Co., Inc. It is PRB's understanding that it is RD's policy to no longer allow third party registrations for SLN registrations.
- Revisions are needed to the PPE section, as required in the IRED.
- An addition must be made to the Engineering Controls section.

RECOMMENDATIONS:

The subject product requires revisions to parent product label to conform with the acute toxicity review, and Agency label policies; and to the SLN label to conform with the IRED. Once these revisions have been submitted and approved by the PM, PRB recommends that the subject product label be accepted for an amended product reregistration (final product reregistration cannot occur until the Agency completes its cumulative risk assessment of the organophosphate pesticides).

Appendix I

PRB Label Analysis

Label Requirement	Acceptable	Not Acceptable	Comments/Recommendations
Restricted Use Pesticide		X	This product meets the criterion for Restricted Use Classification based on data that place it in "Toxicity Category I for eye irritation. In lieu of classifying the product for restricted-use, the product manager may consider requiring alternative labeling such as face shield, goggles, safety glasses and/or gloves if the PM determines that such PPE will mitigate the identified hazards.
Product Name	X		
Company Name and Information	X		PRB recommends that the company's phone number be placed on the label. See Appendix II for suggested placement
Identification Numbers	X		
Net Contents	X		
Ingredients Statement	X		
Precautionary Statements			
KOROC	X		
Signal Word		X	Per the acute toxicity review dated 2/10/03, the signal word section must be revised to read: DANGER PELIGRO
General Heading "Precautionary Statements"	X		
First Aid		X	As per PR Notice 2001-1, the following hotline information should be added to the label: "For additional information in case of emergency call toll free (Telephone Number). See Appendix II for suggested placement.

First aid (con't)			<p>PRB recommends that the Note to Physician also include text that addresses the eye irritation concerns and the presence of a cholinesterase inhibitor and should include the following information:</p> <ul style="list-style-type: none"> -technical information on symptoms, -use of supportive treatments to maintain life functions, -medicine that will counteract the specific physiological effects of the pesticide, -company telephone number to specific medical personnel who can provide specialized medical advice. <p>Note to PM: Please also note that as per PR Notice 2001-1, registrants are encouraged to place the statements in a box.</p> <p>Please see Appendix II for formatting and placement suggestions.</p>
Hazards to Human and Domestic Animals Heading -Precautionary Statements		X	<p>As per the acute toxicity review, the Hazards to Humans and Domestic Animals statements must be modified as specified below:</p> <p>"DANGER Corrosive. Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes. Avoid contact with skin or clothing.."</p> <p>See Appendix II for suggested placement.</p>
-PPE	X		<p>Note to PM: PRB believes that chemical resistant gloves made of barrier laminate, butyl rubber, nitrile rubber, or viton (Category F) are appropriate for this product. PRB has no objection to the registrant retaining the text allowing gloves made of barrier laminate or viton" if they believe these materials are appropriate.</p>
-Engineering Controls	X		
-User Safety Requirements	X		
-User Safety Recommendations	X		
Environmental Hazards	X		
Physical and Chemical Hazards	X		
Directions for Use (FIFRA Text, WPS and Storage and Disposal)			
Header "Directions for Use"	X		See Appendix II for placement.
Violation of Federal Law Text	X		
WPS Text	N/A		

Warranty Information			
Consistency with label instructions/not false and misleading		X	<p>The "Notice of Warranty" statements contain language that negates or detracts from required label statements. For example, the phrase "Seller warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use" imply that the Directions For Use cannot be safely followed by the user, or that some unspecified, label approved uses should be avoided, thereby detracting from the directions. The registrant must specify in the Directions For Use what are the "normal conditions of use" or what "abnormal conditions" should be avoided for the product to be "... fit for the purposes stated in the Directions for Use...". Alternatively, the registrant may delete the objectionable language.</p> <p>The "Notice of Warranty" statements contain over broad statements concerning limitation of liability or immunity from liability ("Seller shall not be responsible for incidental or consequential damages, if any, resulting from a breach of warranty" and "This warranty does not extend to the storage, handling, or use of this product contrary to label instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to Seller..."), as well as purported buyer agreement to assume risk ("Buyer assumes the risk of any such storage, handling or use"). The registrant should be informed that such statements may misleading and may constitute misbranding under FIFRA. OGC has suggested that these statements be preceded by a qualifying phrase such as "To the extent allowable by State law, ..." However, the guidance in Policy and Criteria Notice 2163.1 states that PM's will not, at this time, conduct a detailed review of such liability disclaimers or purported buyer agreement to assume risk; but will inform registrants that approval of the label with such statements should not be construed as a decision by the Agency that the language is not misleading and that the label language might eventually have to be changed. Refer to Policy and Criteria Notice 2163.1 for further information.</p>
General Comments			
None			

Suggested Presentation of Label

RESTRICTED USE PESTICIDE

Product Name

Ingredients.....

EPA Registration and Establishment Numbers

Company Name, Address, Phone Number

Net Contents

KEEP OUT OF REACH OF CHILDREN

SIGNAL WORD

FIRST AID	
IF IN EYES	<ul style="list-style-type: none">•Hold eye open and rinse slowly and gently with water for 15-20 minutes.•Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.•Call a poison control center or doctor for treatment advice.
IF SWALLOWED	<ul style="list-style-type: none">•Call poison control center or doctor immediately for treatment advice.•Have person sip a glass of water if able to swallow.•Do not induce vomiting unless told to do so by the poison control center or doctor.•Do not give anything by mouth to an unconscious person.
IF ON SKIN OR ON CLOTHES	<ul style="list-style-type: none">•Take off contaminated clothing.•Rinse skin immediately with plenty of water for 15-20 minutes.•Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
1.	"In case of emergency call toll free number XXXXX."
2.	"Have the product container or label with you when calling a poison control center or doctor or going for treatment."
NOTE TO PHYSICIAN	

APPENDIX I-A

PRB SLN LABEL ASSESSMENT FOR EPA SLN NO. WA900038

LABEL REQUIREMENTS	ACCEPTABLE	NOT ACCEPTABLE	COMMENTS/RECOMMENDATIONS
State where registration is valid	X		
SLN Directions for Use*	X		
Product Name	X		
Name and Address of 24(c) Registrant	X		
EPA Reg. No. (If applicable)	X		
SLN Registration No.	X		
Statement prohibiting use inconsistent with label(s)	X		
*DIRECTIONS FOR USE			
General Instructions and Information	N/A		
General Precautions and Restrictions	X		
Application Instructions	X		
GENERAL COMMENTS			
3rd Party Registrant		X	The registrant for this SLN registration is a third party, Washington Bulb Co., Inc. It is PRB's understanding that it is RD's policy to no longer allow third party registrations for SLN registrations.

LABEL REQUIREMENTS	ACCEPTABLE	NOT ACCEPTABLE	COMMENTS/RECOMMENDATIONS
PPE		X	<p>Per the IRED(Page 32) the PPE section must be revised to read:</p> <p>“Personal Protective Equipment (PPE)</p> <p>Mixers, loaders, applicators and other handlers must wear:</p> <p>Some materials that are chemical resistant to this product are barrier laminate, butyl rubber, nitrile rubber, or viton. If you want more options, follow the instructions for category F on an EPA chemical-resistant category selection chart.*</p> <p>Mixer, loaders, applicators and other handlers must wear:</p> <ul style="list-style-type: none"> -Coveralls over long sleeved shirt and long pants, -Chemical resistant footwear plus socks, -Chemical resistant gloves, --Chemical resistant apron (for mixers and loaders).” <p>Note to PM:</p> <p>PRB believes that chemical resistant gloves made of barrier laminate, butyl rubber, nitrile rubber, or viton (category F) are appropriate for this product. PRB has no objection to the registrant using the text “gloves made of barrier laminate or viton” [category G] used for the parent product, if it is believed that these materials are appropriate.</p> <p>The text “In addition, handlers must wear coveralls over long sleeved shirt and pants, chemical resistant footwear plus socks, and chemical resistant gloves... apparatus (SCBA) (MSHA/NIOSH approval number prefix TC-3F” must be revised and should be relocated to the engineering controls section described below.</p>

Non-WPS Text	N/A		
Storage and Disposal	X		
Directions for Use (General Instructions and Information)			
Chemigation/Prohibition	N/A		
Spray Drift Labeling	N/A		
General Information (non-site specific information on uses, pests, mixing and loading, tank mixing, etc...)	X		See Appendix II for suggested subheading and placement.
General Precautions and Restrictions	X		See Appendix II for suggested placement.
Direction for Use (Application Instructions)			
Application Instructions	X		Note to PM: The registrant should correct the typographical error on the top of Page 5 of the draft label. " <u>STRORED</u> " should be revised to read "STORED." See Appendix II for suggested subheading and placement.

LABEL REQUIREMENTS	ACCEPTABLE	NOT ACCEPTABLE	COMMENTS/RECOMMENDATIONS
Engineering Controls		X	<p>Per the IRED (Page 33), the text in bold type below must be added to Engineering Controls:</p> <p>“Engineering Controls</p> <p>Application must only be made with the use of a stationary or cart-mounted fogging device which, when activated, function automatically without an operator present. In addition:</p> <p>Handlers must wear the following PPE:</p> <ul style="list-style-type: none"> -Coveralls over long sleeved shirt and long pants, -Chemical resistant footwear plus socks, -Chemical resistant gloves, <p>In addition, mixers and loaders must wear chemical resistant apron.</p> <p>In addition to the above,</p> <ul style="list-style-type: none"> -handlers must have available to them for use in case they must enter the area during treatment, or before ventilation requirements have been met: -chemical resistant headgear, and -a self-contained breathing apparatus (SCBA)(MSHA/NIOSH approval number prefix TC-3F).”
Entry Restrictions	X		
Waiver of Liability Statement	N/A		

Insert a Note to Physician that addresses eye irritation and the presence of a cholinesterase inhibitor. The following statements are suggested types of information that may be inserted, if applicable:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company phone number to medical personnel who can provide specialized medical advice.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

PPE

USER SAFETY REQUIREMENTS

ENGINEERING CONTROLS

USER SAFETY RECOMMENDATIONS

ENVIRONMENTAL HAZARDS

PHYSICAL AND CHEMICAL HAZARDS

DIRECTIONS FOR USE

It is a Violation of Federal Law.....

STORAGE AND DISPOSAL

General Information (non-site-specific)

The list of insects controlled with Actellic 5E Insecticide may be moved to this section.

General Precautions and Restrictions

APPLICATION INSTRUCTIONS (site-specific)

WARRANTY STATEMENT



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 1381-170	2. EPA Product Manager John Hebert	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Actellic 5E Insecticide	PM# 7	
5. Name and Address of Applicant (Include ZIP Code) Agrilience, LLC c/o Alice Walker 481 Country Club Drive Senatobia, Mississippi 38668 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

NOTIFICATION Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

JUN 21 2005

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification to add the descriptor, "Low Odor Formulation," below the brand name of the product.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name ALICE WALKER, Ph.D		Title Regulatory Consultant		Telephone No. (Include Area Code) 662-562-5995	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Consultant			
4. Typed Name ALICE WALKER, PhD		5. Date May 18, 2005			

Alice Walker, Ph.D.

REGULATORY CONSULTING • 481 COUNTRY CLUB DRIVE • SENATOBIA, MS 38668

Certified Mail

May 18, 2005

Document Processing Desk (Notif)
Office of Pesticide Programs (7505C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, DC 20460

NOTIFICATION

JUN 2 1 2005

Re: Actellic 5E Insecticide
EPA Reg. No. 1381-170

Attn: Sherada Hobgood

This correspondence will constitute notification from Agrilience, LLC to add the descriptor, "Low Odor Formulation," below the brand name of the above-referenced product registration.

To this end, please find enclosed one copy of new labeling along with the appropriate application form.

I believe this notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under section 12 and 14 of FIFRA.

Thank you for adding this notification to the registration record for this product.

Sincerely,



Alice Walker, Ph.D.
Regulatory Agent for
AGRILIENCE, LLC

Enclosures
cc: Mr. Gary Halvorson



ACTELIC® 5E INSECTICIDE LOW ODOR FORMULATION

FOR CONTROL OF INSECTS ON STORED CORN AND GRAIN SORGHUM
(Including Bulk or Bagged Seed)

ACTIVE INGREDIENT:

Pirimiphos-methyl

0-(2-(diethylamino)-6-methyl-4-pyrimidinyl)0,0-dimethyl phosphorothioate57%

INERT INGREDIENTS:43%

TOTAL.....100%

Actellic 5E Insecticide contains 5 pounds active ingredient per gallon.

KEEP OUT OF REACH OF CHILDREN WARNING

NOTIFICATION

JUN 2 1 2005

FIRST AID

- | | |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| If in eyes | <ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice. |
| If swallowed | <ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person. |
| If on skin or clothing | <ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice. |
| If inhaled | <ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice. |

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. **NOTE TO PHYSICIAN:** Inducing vomiting as first aid for this substance may result in increased risk of chemical pneumonia or pulmonary edema caused by aspiration of the hydrocarbon solvent. Vomiting should be induced only under professional supervision. Atropine is antidotal for cholinesterase inhibition. Give 2 mg. of atropine intramuscularly or subcutaneously and repeat if symptoms of poisoning reappear. Pralidoxime (2 PAM) may be given if available. Give 1 gram intramuscularly or intravenously and repeat as necessary.

See side panel for additional precautionary statements.

EPA Reg. No. 1381-170

EPA Est No. _____

Agriliance, LLC
P.O. Box 64089
St. Paul, MN 55164-0089

Net Contents
_____ Gals.
0/E18/5

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING**

Causes eye irritation. Do not get in eyes. Wear goggles or face shield when handling.

Harmful if swallowed, inhaled, or absorbed through the skin. Avoid breathing vapors or spray mist. Keep container closed. Wear rubber gloves when handling concentrate.

Causes skin irritation. Do not get on skin or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal zones below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of waste.

In case of a significant spill, call CHEMTREC (800) 424-9300.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

STORAGE AND DISPOSAL

PROHIBITIONS: Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

STORAGE: Store in a cool place and protect from freezing. If accidentally frozen, reconstitute by gently warming to room temperature and thoroughly mixing contents. Keep container closed when not in use.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL:

Metal Containers: Triple rinse(or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, by other procedures approved by State and local authorities.

Plastic Containers: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

APPLICATION DIRECTIONS

ADMIXTURE OR TOP DRESSING

(Only ONE application method may be used per load.)

The best practice to protect stored corn and grain sorghum from insect infestation is to use an admixture treatment of Actellic 5E Insecticide. However, as it may not always be possible to move grain, a surface treatment of Actellic 5E Insecticide will help prevent the establishment of migrating insects. The top dressing application will not substitute for a treatment of the entire amount of stored corn or grain sorghum. But within your current stored grain management system, it will help protect the surface from invasion by insects.

Notice: Either treatment should only be used if the corn or grain sorghum has not previously received an application of Actellic 5E Insecticide.

ADMIXTURE TREATMENT

Apply spray solution uniformly with suitable application equipment as grain enters storage or export containers. Select nozzle size and operating pressure to adjust the application rate with flow of grain. Prepare desired dilution of Actellic 5E Insecticide in spray tank and mix well. Make sure spray solution stays mixed, especially in large holding tanks. Apply the spray solution as a coarse, uniform low pressure spray in order to minimize drift. Shield nozzle if necessary. Apply the specified amount of Actellic 5E Insecticide in 5 gallons of water or 3-5 gallons of at least twice refined soybean oil to each 30 tons (60,000 pounds) of grain according to the following rates.

	Fluid Ounces	ppm Concentration
Shelled Corn (field corn, seed corn, popcorn)	9.2-12.3	6-8
Grain Sorghum	9.2-12.3	6-8
Grain	No. of Bushels Approximately Equal to 30 Tons of Grain	
Shelled Corn (field corn, seed corn, popcorn)	1,071	
Grain Sorghum	1,071	

TOP DRESSING TREATMENT

To each 1,000 square feet of grain surface, apply 3 fluid ounces of Actellic 5E Insecticide diluted in 2 gallons of water. The treatment should be split as follows: Spray half of the mixture evenly over the surface and rake into the grain to a depth of 4 inches. Apply the remaining half of the mixture (1 gallon) to the raked surface.

Before making a surface application of Actellic 5E Insecticide, it will be necessary to remove any webbing and break up crusting that exists on the grain surface. If high numbers of Indian Meal Moth worms (2-3 per sq ft) exist, it will be best to remove the webbing, fumigate, and then apply Actellic 5E Insecticide as a surface application. Mix the following amount of Actellic 5E Insecticide with 2 gallons of water for a total mixture to treat 1,000 sq ft of grain surface:

	Fluid Ounces	ppm Concentration
Corn and Sorghum	3.0	8

INSECTS CONTROLLED WITH ACTELLIC 5E INSECTICIDE

COLEOPTERA		LEPIDOPTERA
Cigarette beetle	Maize weevil	Almond moth
Confused flour beetle	Merchant grain beetle	Angoumois grain moth
Corn sap beetle	Red flour beetle	Indian meal moth
Flat grain beetle	Rice weevil	
Granary weevil	Sawtoothed beetle	
Hairy fungus beetle		

REMARKS AND PRECAUTIONS

- Grains treated with Actellic 5E Insecticide at rates indicated on this label may be used immediately for any food or feed purpose.
- Do not make more than one application per crop.
- Calibrate spray equipment and periodically check in order to ensure proper spray rates.
- Do not store diluted Actellic 5E Insecticide in spray tank more than 48 hours before use.
- Avoid severely dusty application sites.
- Applications of Actellic 5E Insecticide include stored bulk or bagged seed corn and sorghum grain.
- Intended for storage insect control only. Not meant to be used for control of soil insects.

Notice of Warranty

Seller warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use. SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, NOR IS ANY REPRESENTATIVE OF SELLER AUTHORIZED TO MAKE ANY SUCH WARRANTY OR MODIFY THESE TERMS. This warranty does not extend to the storage, handling or use of this product contrary to label instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to Seller, and Buyer assumes the risk of any such storage, handling or use. Seller shall not be responsible for incidental or consequential damages, if any, resulting from a breach of warranty.

Actellic® is a registered trademark of a Syngenta Group Company.

AgriSolutions™ is a trademark of Agrilience, LLC.



Request for Time Extension on Pirimiphos-Methyl IRED Label Changes

AgriLiance is making a formal request for a time extension to the requirements for the amended label language pertaining to use of closed systems for admixture application of Pirimiphos-methyl and the prohibition of marketing 64-ounce containers and less for admixture treatment to grain.

This request is based on two factors. First, is the great need for pest protection for on-farm stored grain. The USDA estimates growers lose millions of dollars each year to stored-grain insects and the control alternatives are few. Combined with non-chemical methods, corn and sorghum growers need chemical alternatives for an effective IPM strategy to reduce losses to the stored grain insect complex. The only chemical methods left to them are malathion, which has experienced extensive insect resistance in recent years, fumigants, and Pirimiphos-methyl. The only effective "preventative" option then is Pirimiphos-methyl as fumigants are "curative" products or only used when infestation is present. Due to the cost of the material and treatment rate, individual grower's preference for commercial package sizes would be the 26 or 64 ounce container. To leave these growers (mostly small family farmers) with only the option of top dressing would take away a significant tool in their stored insect control program.

The second reason is the recent completion of the three-week dermal toxicity study with Pirimiphos-methyl. The results of this study indicate to us (because of clear NOAELs) that the risk assessment for mixers/loaders/handlers will change once this data is evaluated with the other data available thus far to the Agency. One of the Agency's reasons for requirement of these risk mitigation measures is the lack of sound studies that would change the now assumed 100% dermal absorption factor used in the current risk assessment. The summary section of the audited draft report is appended to this request. We urge the Agency to give the review of this additional data priority for a further refined risk estimate of worker exposure. In addition, we request the Agency to consider our previous application for bin disinfecting in light of the refined risk estimates. We expect the final report on the dermal toxicity study to be submitted to the agency by the end of August of this year.

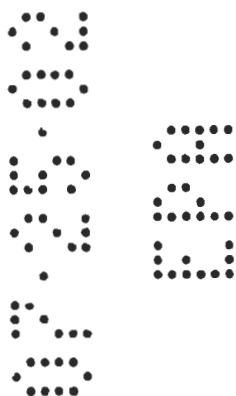
We therefore request that these label changes (specifically the requirement for closed systems to containers greater than 64 oz. with admixture use and the deletion of admixture use to containers of 64 oz. or less) be extended for one year - to April 2004. In light of the fact that if we are to change labels for the 2003 use season (or by April 2003 according to the IRED) we need to gear up and have labels and closed systems in place by the end of the year. The Agency will need some time to review the new data. Therefore it is unlikely that the Agency would advise AgriLiance of a revised risk assessment for occupational workers before these labeling measures were already in place. We would be forced to change the labeling twice in one year subsequently resulting in two completely different labels in the market place or facing an expensive recall and relabeling program.



Attachment A

Audited Draft Report – Not submitted as a study

Used for time extension request only.



AUDITED DRAFT

Volume 1 of 2
(Text and Tables 1-38)

STUDY TITLE

A THREE-WEEK DERMAL TOXICITY
STUDY OF PRIMIPHOS-METHYL IN RATS

STUDY NUMBER

WIL-400005

DATA REQUIREMENT

OPPTS Guideline 870.3200
OECD Guideline Section 410

STUDY DIRECTOR

Thomas P. O'Neill, B.S.

STUDY INITIATION DATE

January 31, 2002

STUDY COMPLETION DATE

PERFORMING LABORATORY

WIL Research Laboratories, Inc.
1407 George Road
Ashland, OH 44805-9281

SPONSOR

Agriliance
5600 Cenex Drive
Inner Grove Heights, MN 55077

I. SUMMARY**1.1. OBJECTIVE**

The objective of the study was to evaluate the possible toxic effects of pirimiphos-methyl when administered dermally to rats five days per week for 3 weeks.

1.2. STUDY DESIGN

Pirimiphos-methyl in the vehicle, 0.5% carboxymethylcellulose, was administered dermally once daily for 3 weeks, 5 days per week, to three toxicology groups (Groups 2-4) and three cholinesterase groups (Groups 2A-4A) of CrI:CD[®](SD)IGS BR rats. Dosage levels were 2, 4 and 25 mg/kg/day, and the dose volume was 1 mL/kg for all groups. Concurrent control groups (Groups 1 and 1A) received the vehicle on a comparable regimen. Groups 1-4 consisted of 10 animals/sex/group and groups 1A-4A each consisted of 5 animals/sex/group.

For toxicology assessment, all animals were observed twice daily for mortality and moribundity. Clinical examinations were performed daily and detailed physical examinations were performed weekly. Individual body weights and food consumption were recorded weekly. Clinical pathology evaluations (hematology, serum chemistry and urinalysis) were performed on all animals euthanized at the scheduled necropsy (study week 3). Ophthalmic examinations were performed during study weeks -1 and 3. Following 3 weeks of dose administration, all toxicology group rats were euthanized. Complete necropsies were conducted on all animals, and selected organs were weighed. Selected tissues were examined microscopically from all animals.

For cholinesterase evaluation, blood samples were collected from all animals between 8:00 and 10:00 a.m. on study days 1 and 19. All animals were euthanized, and brains were collected for cholinesterase evaluation following the final blood collection (study day 19).

1.3. RESULTS

All animals survived to the scheduled necropsy. There were no test article-related clinical findings and no test article-related signs of dermal irritation. Food consumption, hematology, serum chemistry, red blood cell or brain cholinesterase and urinalysis parameters were unaffected by test article administration. No test article-related ophthalmic findings were noted, and no test article-related macroscopic or microscopic changes were observed at the scheduled necropsy. No test article-related changes were noted in the 2 and 4 mg/kg/day groups.

Test article-related effects noted in the 25 mg/kg/day group consisted of:

- Overall mean body weight gains were lower throughout the study in males only. These lower gains were not considered to be adverse.
- Mean plasma cholinesterase levels in the 25 mg/kg/day group males and females were lower than the control group values on study days 1 (26%, males; 25%, females) and 19 (28%, males; 53%, females).

1.4. CONCLUSIONS

Based on the results of this study, the no-observed-effect level (NOEL) for local irritation of pirimiphos-methyl to rats for 3 weeks was 25 mg/kg/day, applied to a mean body surface area of 8.2%. The no-observed-adverse-effect level (NOAEL) for systemic toxicity was 25 mg/kg/day, applied to a mean body surface area of 8.2%. The no-observed-effect level (NOEL) for red blood cell and brain cholinesterase was 25 mg/kg/day, applied to a mean body surface area of 8.2%. The NOEL for plasma cholinesterase was 4 mg/kg/day, applied to a mean body surface area of 7.8%.

Audited Draft

DP BARCODE: D288484

CASE: 018282
SUBMISSION: S628359

DATA PACKAGE RECORD
BEAN SHEET

DATE: 02/21/03
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 674 8 MNTH RESP-PROD SPC DATA
RANKING : 10 POINTS ()
CHEMICALS: 108102 Pirimiphos-methyl (ANSI) 57.0000%

ID#: 001381-00170 ACTELIC 5E INSECTICIDE
COMPANY: 001381 AGRILIANCE, LLC
PRODUCT MANAGER: 04 MEREDITH LAWS 703-308-9366 ROOM: CM2 282
PM TEAM REVIEWER: VENUS EAGLE-KUNST 703-308-8045 ROOM: CM2 117 M
RECEIVED DATE: 01/16/03 DUE OUT DATE: 07/15/03

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 288484 EXPEDITE: N DATE SENT: 02/21/03 DATE RET.: / /
CHEMICAL: 108102 Pirimiphos-methyl (ANSI)
DP TYPE: 001 Submission Related Data Package
CSF: N LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 05/22/03
DIV : SRRD	/ /	/ /	NEGOT DATE: / /
BRAN: PRB	/ /	/ /	PROJ DATE: / /
SECT: IO	/ /	/ /	
REVR : Locals 2	126/03	5/18/05	
CONTR:	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

Attention: Label Review Team

Please conduct the preliminary label assessment for this pirimiphos-methyl product. Note, this product is also the parent of SLN WA9000380, which is also attached for your review. Appropriate science reviews and RED chapt. are attached.

Thanks,
Venus

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
288085	PRB/IO	01/30/03	04/30/03	Y	Y	Y
288087	PRB/IO	01/30/03	04/30/03	Y	Y	Y

DATA PACKAGE BEAN SHEET

Date: 08-Dec-2003

Page 1 of 2

12/15

***** Registration Information *****Registration: PDCI-108102-0240Short Name: PDCI(11,01)Company: 1381 -AGRILIANCE, LLCRisk Manager: RM 81 - Linda - Propst - (703) 308-8165 Room# CM-2 108B

Risk Manager Reviewer: _____

Type of Data Callin: Product SpecificIngredients: 108102, Pirimiphos-methylGuidelines: Storage stability of productCorrosion characteristics***** Data Package Information *****Expedite: ☐ Yes ☒ NoDate Sent: 08-Dec-2003

Due Back: _____

DP Ingredient: 108102, Pirimiphos-methylDP Title: resubmission of 63-17 & -20 for 1381-170CSF Included: ☒ Yes ☐ NoLabel Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To**Date In****Date Out**Organization: SRRD / PRB

Administrative Due Date: _____

Team Name: _____

Negotiated Due Date: _____

Reviewer Name: _____

Projected Completion Date: _____

Contractor Name: _____

***** Studies Sent for Review *****

Printed on Page 2

***** Additional Data Package for this Decision *****

No Additional Data Packages

***** Data Package Instructions *****

Attention: Maria

Please review agrilance resubmission of 63-17 and -20 data (MRID46118001) in response to your previous review dated 2/13/02.

Thanks - Venus

DP#: (296750)

*** Studies Sent for Review ***

Decision#: (0)

46118001	Wo, C. (2003) Storage Stability and Corrosion Characteristics: Actellic 5E Insecticide. Project Number: 12790, P800. Unpublished study prepared by Product Safety Labs. 30 p.	830.6317/Storage stability of prod
46118001	Wo, C. (2003) Storage Stability and Corrosion Characteristics: Actellic 5E Insecticide. Project Number: 12790, P800. Unpublished study prepared by Product Safety Labs. 30 p.	830.6320/Corrosion characteristic



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PB all accept
TDX.

February 10, 2003

MEMORANDUM:

Subject: EPA Reg. No.: 1381-170/Actellic 5E Insecticide
DP Barcode: D288087
Case No.: 2535

From: Marianne Lewis, Biologist
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

To: Venus Eagle-Kunst, CRM
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

Applicant: Agriliance, LLC
P.O. Box 64089
St. Paul, MN 55164-0089

Marianne Lewis 2/10/03

FORMULATION FROM EPA Reg. No. 1381-170 LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Pirimiphos-methyl	
0-(2-(diethylamino)-6-methyl-4-pyrimidinyl)0,0-dimethyl phosphorothioate	57.0%
<u>Inert Ingredient(s):</u>	43.0%
Total	100.0%

BACKGROUND: In the 8 month response to the Pirimiphos-methyl RED, the registrant has submitted acute toxicity studies to support the reregistration of their product, EPA Reg. No. 1381-170. The MRID's are as follows: 458404-02 (81-1), 458404-03 (81-2) 458404-04 (81-3), 458404-05 (81-4), 458404-06 (81-5), 458404-07 (81-6). The studies were conducted by Product Safety Labs and the material used in the studies was the subject product.

RECOMMENDATIONS:

- The acute toxicity studies submitted are acceptable to support the reregistration of EPA Reg. No. 1381-170.

The acute toxicity profile for EPA Reg. No. 1381-170 is currently:

Acute Oral	III	Acceptable
Acute Dermal	IV	Acceptable
Acute Inhalation	IV	Acceptable
Primary Eye	I	Acceptable
Primary Dermal	III	Acceptable
Skin Sensitization	non sensitizer	Acceptable

NOTE: The acute toxicity requirements have been satisfied for the subject product.

DATA REVIEW FOR ACUTE ORAL TOXICITY (§81-1, 870.1100)

Product Manager: Meredith Laws, 04
MRID No.: 458404-02

Reviewer: Marianne Lewis
Study Completion Date: 1/7/03
Report No.: 12784

Testing Facility: Product Safety Labs
Author: D.Merkel

Quality Assurance (40 CFR §160.12): Included

Test Material: Actellic 5E Insecticide, EPA Reg. No. 1381-170, amber liquid
Method: Up and Down Procedure

Species: Sprague-Dawley albino rat
Age: young adult
Weight: females = 165 - 190 g
Source: Ace Animals, Inc.

Conclusion:

1. **LD₅₀ (mg/kg):** >2000 mg/kg

2. **Tox. Category:** III

Classification: Acceptable

Procedure (Deviations from §81-1): none

Results:

Dosage (mg/kg)	Number Deaths/Number Tested		
	Males	Females	Combined
2000	N/A	1/5	N/A

Method: All of the test animals were fasted overnight prior to the administration of the test substance. The initial animal tested was given the test material using a stainless steel ball-tipped gavage needle attached to the appropriate syringe. The feed was replaced approx. 3 to 3.5 hours after dosing. Based on the survival of the first animal in the 24 to 48 hour period following dosing, four more animals were dosed in sequence at a dose level of 2,000 mg/kg. The test animals were observed for 14 days after dosing.

Observations: Clinical signs in the survivors: 4/4 ano-genital staining. Decedent displayed ano-genital staining, hypoactivity, prone position, death within 24 hours.

Gross Necropsy: Survivors had no gross abnormalities. The decedent had moderately red lungs and black-red intestines.

DATA REVIEW FOR ACUTE DERMAL TOXICITY (§81-2, 870.1100)

Product Manager: Meredith Laws, 04
MRID No.: 458404-03

Reviewer: Marianne Lewis
Study Completion Date: 1/7/03
Report No.: 12785

Testing Facility: Product Safety Labs
Author: D.Merkel

Quality Assurance (40 CFR §160.12): Included

Test Material: Actellic 5E Insecticide, EPA Reg. No. 1381-170, amber liquid

Species: Sprague-Dawley derived albino rat
Weight: males = 230 - 264 g; females = 192 - 215 g
Age: young adult
Source: Ace Animals, Inc.

Summary:

1. **LD₅₀ (mg/kg):** >5000 mg/kg

2. **Tox. Category:** IV

Classification: Acceptable

Procedure (Deviations From §81-2): none

Results:

Reported Mortality

DOSAGE (mg/kg)	(number deaths/number tested)		
	Males	Females	Combined
5000	0/5	0/5	0/10

Observations: Twenty four hours prior to application, the dorsal area and trunk of each animal was clipped free of hair. The test material was spread evenly over a dose area of approx. 2 x 3 inches (approx. 10% of the body surface) and covered with a 2 x 3 inch, 4-ply gauze pad. The pad and the entire trunk of each animal were wrapped with 3 inch Durapore tape. After 24 hours, the pads were removed and the sites wiped with water and a clean towel.

All animals survived, gained weight, and appeared active and healthy.

Gross Necropsy Findings: No gross abnormalities were noted.

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3, 870.1300)

Product Manager: Meredith Laws, 04
MRID No.: 458404-04

Reviewer: Marianne Lewis
Study Completion Date: 1/7/03
Report No.: 12786

Testing Facility: Product Safety Labs
Author: D.Merkel

Quality Assurance (40 CFR §160.12): Included

Test Material: Actellic 5E Insecticide, EPA Reg. No. 1381-170, amber liquid

Species: Sprague-Dawley derived albino rat
Weight: males = 280 - 321 g; females = 216 - 231 g
Age: young adult
Source: Ace Animals, Inc.

Summary:

1. **LC₅₀ (mg/L):** > 2.02 mg/L
2. **MMAD:** **GSD:** 1.80
3. **Tox. Category:** IV **Classification:** Acceptable

Procedure (Deviation From §81-3): none

Results: **Reported Mortality**

Exposure Concentration	(Number Deaths/Number Tested)		
	Males	Females	Combined
2.02 mg/L	0/5	0/5	0/10

Chamber Atmosphere		
Dose Level	MMAD	GSD
2.02 mg/L	2.9 µm	1.80

Chamber Environment	Dose levels
	2.02 mg/L
Chamber Volume	150 L
Airflow	45.7 Lpm
Temperature (°C)	21 - 23
Relative Humidity (%)	45 - 80

Clinical Observations: Upon removal from chamber: 5/10 hypoactive, 1/10 irregular respiration. From day 1 to the end of the study all test animals were active and healthy.

Gross Necropsy Findings: No gross abnormalities were noted.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: Meredith Laws, 04
MRID No.: 458404-05

Reviewer: Marianne Lewis
Study Completion Date: 1/7/03
Report No.: 12787

Testing Facility: Product Safety Labs
Author: D.Merkel

Quality Assurance (40 CFR §160.12): Included

Test Material: Actellic 5E Insecticide, EPA Reg. No. 1381-170, amber liquid

Dosage: 0.1 ml
Species: New Zealand albino rabbit
Sex: 2 males, 1 female
Weight: not given
Age: young adult
Source: Millbrook Breeding Labs

Summary:

1. Toxicity Category: I

2. Classification: Acceptable

Procedure (Deviations From §81-4): none

Results:

OBSERVATIONS	(number "positive"/number tested)									
	Hours				Days					
	1	24	48	72	4	7	10	15	17	21
Corneal Opacity	0/3	3/3	3/3	3/3	3/3	3/3	2/3	2/3	2/3	2/3
Iris	3/3	3/3	3/3	3/3	3/3	2/3	1/3	1/3	1/3	0/3
Conjunctivae										
Redness	3/3	3/3	3/3	3/3	3/3	2/3	2/3	0/3	0/3	0/3
Chemosis	3/3	3/3	3/3	3/3	0/3	0/3	0/3	0/3	0/3	0/3
Discharge	3/3	3/3	3/3	3/3	0/3	0/3	0/3	0/3	0/3	0/3

Opacity: From 24 to 72 hours 3/3 had scattered or diffuse areas of opacity. On day 4, 2/3 had scattered or diffuse areas of opacity and 1/3 had easily discernible translucent areas of opacity.

On day 7, 1/3 had scattered or diffuse areas of opacity and 1/3 had opalescent areas of opacity with no details of the iris visible. By day 10, 1/3 had scattered or diffuse areas of opacity and 1/3 had easily discernible translucent areas of opacity. From day 15 to the end of the study, 2/3 had scattered or diffuse areas of opacity.

Iris: From 1 hour to day 4, 3/3 had iritis. On day 7, 2/3 demonstrated iritis. From day 10 to day 17 1/3 demonstrated iritis.

Conjunctivae: At 1 hour, 2/3 had diffuse crimson red conjunctivae, 2/3 had obvious swelling with partial eversion of the lids, and 2/3 had discharge with moistening of lids and hairs just adjacent to lids. At 24 hours, 1/3 diffuse crimson red conjunctivae, 2/3 beefy red conjunctivae, 1/3 obvious swelling with partial eversion of lids, 2/3 swelling with lids about half closed, 3/3 discharge with moistening of lids and hairs & considerable area around eye. By 72 hours, 1/3 diffuse crimson red conjunctivae, 2/3 beefy red conjunctivae, 3/3 obvious swelling with partial eversion of lids, 1/3 discharge w/moistening of lids/hairs just adjacent to lids, and 2/3 discharge w/moistening of lids & hairs & considerable area around eye. On day 4, 3/3 diffuse crimson red conjunctivae. By day 7 through day 10, 2/3 diffuse crimson red conjunctivae. By day 15, all conjunctival irritation had cleared.

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: Meredith Laws, 04
MRID No.: 458404-06

Reviewer: Marianne Lewis
Study Completion Date: 1/7/03
Report No.: 12788

Testing Facility: Product Safety Labs
Author: D.Merkel

Quality Assurance (40 CFR §160.12): Included

Test Material: Actellic 5E Insecticide, EPA Reg. No. 1381-170, amber liquid

Dosage: 0.5 ml
Species: New Zealand albino rabbit
Age: young adult
Sex: 2 males, 1 female
Weight: not stated
Source: Millbrook Breeding Labs

Summary:

1. Toxicity Category: III

2. Classification: Acceptable

Procedure (Deviations From §81-5): none

Results: Twenty four hours prior to application, the dorsal area and trunk of each test animal was clipped free of hair. The test material was applied to one 6 cm² intact dose site on each animal and covered with a 1 x 1 inch, 4-ply gauze pad. The pads and trunks were then wrapped with semi-occlusive 3 inch Micropore tape. After 4 hours, the pads and wrappings were removed and the test sites wiped with water and clean towels.

From 1 to 48 hours, 3/3 had well defined erythema. At 72 hours, 2/3 had well defined erythema. By day 7, 2/3 had very slight erythema and 2/3 exhibited desquamation. On day 10, all erythema had cleared but desquamation was still present in 2/3 test animals.

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)

Product Manager: Meredith Laws, 04
MRID No.: 458404-07

Reviewer: Marianne Lewis
Study Completion Date: 1/7/03
Report No.: 12789

Testing Facility: Product Safety Labs
Author: D.Merkel

Quality Assurance (40 CFR §160.12): Included

Test Material: Actellic 5E Insecticide, EPA Reg. No. 1381-170, amber liquid

Positive Control Material: HCA, historical study PSL Study #12371 8/15/02

Species: Hartley albino guinea pig
Weight: females = 344 - 494 g
Age: young adult
Source: Elm Hill Breeding Labs

Method: Buehler

Summary:

- 1. This Product is a non sensitizer**
- 2. Classification:** Acceptable

Procedure (Deviation From §81-6): none

Procedure: A group of animals were used to determine the highest non-irritating concentration (HNIC) of the test substance prior to the challenge dose. The HNIC for the test substance was determined to be 75% w/w solution in mineral oil.

The test animals were induced with 0.4 ml of 100% test material once a week for three weeks using a 25 mm Hill Top Chamber. Twenty four and 48 hours after each induction dose the animals were scored for irritation. Two weeks after the last induction dose, 0.4 ml of 75% w/w of the test material in mineral oil was used to challenge the test animals. Twenty four and 48 hours after the challenge the animals were evaluated for sensitization.

One group of 10 animals were used as naive control. These animals received only the challenge doses of the test material.

Results: Twenty four hours after the first induction dose for the test material-induced animals, 9/20 exhibited very faint erythema. After the second induction dose, 8/20 exhibited very faint erythema. After the third induction dose, 13/20 exhibited very faint erythema at the test site.

Twenty four hours after challenge, 8/20 test material-induced animals exhibited very faint erythema and at 48 hours no irritation was seen.

At 24 hours, in the naive control group of animals challenged with the test material, 3/10 exhibited very faint erythema.

ACUTE TOX ONE-LINER

1. PC CODE: 108102
2. CURRENT DATE: February 6, 2003
3. TEST MATERIAL: Actellic 5E Insecticide, EPA Reg. No. 1381-170, amber liquid
Pirimiphos-methyl:57.0%

Study/Species/ Lab/Study#/Date	MRID #	Results	Tox. Cat.	Core Grade
acute oral toxicity/rat/Product Safety Labs/12784/1-7-03	45840402	LD ₅₀ > 2000 mg/kg	III	A
acute dermal toxicity/rat/ Product Safety Labs/12785/ 1-7-03	45840403	LD ₅₀ > 5000 mg/kg	IV	A
acute inhalation toxicity/rat/ Product Safety Labs/12786/ 1-7-03	45840404	LC ₅₀ > 2.02 mg/L MMAD = 2.9 µm; GSD = 1.80	IV	A
primary eye irritation/rabbit/ Product Safety Labs/12787/ 1-7-03	45840405	Opacity: From 24 - 72 hrs 3/3 scattered/diffuse areas of opacity. On day 4, 2/3 scattered/diffuse areas of opacity & 1/3 easily discernible translucent areas of opacity. On day 7, 1/3 scattered/diffuse areas of opacity & 1/3 opalescent areas of opacity w/no details of the iris visible. By day 10, 1/3 scattered or diffuse areas of opacity & 1/3 easily discernible translucent areas of opacity. From day 15 to end of study, 2/3 scattered/diffuse areas of opacity.	I	A
primary dermal irritation/ rabbit/Product Safety Labs/ 12788/1-7-03	45840406	From 1 to 48 hrs, 3/3 well defined erythema. At 72 hrs, 2/3 well defined erythema. By day 7, 2/3 very slight erythema & 2/3 desquamation. On day 10, all erythema had cleared but desquamation was still present in 2/3.	III	A
skin sensitization/guinea pig/ Product Safety Labs/12789/ 1-7-03	45840407	non sensitizer	--	A

Core Grade Key: A = Acceptable; S = Supplementary; U = Unacceptable, V = self-Validated

LABELING:

ID #: 001381-00170 **ACTELIC 5E INSECTICIDE**

RESTRICTED USE CLASSIFICATION RECOMMENDED:

Due to primary eye irritation toxicity category.

The PM Team should decide if restricted use classification is necessary or if alternative labeling will allay the requirement for restricted use classification.

SIGNAL WORD: **DANGER** **PELIGRO**

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Corrosive. Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes. Avoid contact with skin or clothing. Wear long-sleeved shirt and long pants, socks and shoes, protective eyewear (goggles, face shield, or safety glasses), and chemical resistant gloves (such as barrier laminate, butyl rubber, nitrile rubber, viton, selection category F*). Wash thoroughly with soap and water after handling.

*If the selection category F gloves do not provide adequate protection for this product, the registrant should indicate a specific glove category from the EPA chemical resistance glove selection chart that will provide adequate protection.

FIRST AID:

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Users should remove contaminated clothing and wash clothing before reuse.

Note to CRM/PM/Registrant:

The proposed label should contain a Note to Physician which addresses the category I primary eye irritation toxicity and the presence of a cholinesterase inhibitor. The following statements are some suggested types of information that could be included, if applicable, in the Note to Physicians:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

DP BARCODE: D288087

CASE: 018282
SUBMISSION: S628359

DATA PACKAGE RECORD
BEAN SHEET

DATE: 01/30/03
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 674 8 MNTH RESP-PROD SPC DATA

RANKING : 10 POINTS ()

CHEMICALS: 108102 Pirimiphos-methyl (ANSI)

57.0000%

ID#: 001381-00170 ACTELIC 5E INSECTICIDE

COMPANY: 001381 AGRILIANCE, LLC

PRODUCT MANAGER: 04 MEREDITH LAWS

703-308-9366

ROOM: CM2

282

PM TEAM REVIEWER: VENUS EAGLE-KUNST

703-308-8045

ROOM: CM2

117 M

RECEIVED DATE: 01/16/03

DUE OUT DATE: 07/15/03

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 288087

EXPEDITE: N

DATE SENT: 01/30/03

DATE RET.: / /

CHEMICAL: 108102 Pirimiphos-methyl (ANSI)

DP TYPE: 001 Submission Related Data Package

CSF: Y

LABEL: Y

ASSIGNED TO

DATE IN

DATE OUT

ADMIN DUE DATE: 04/30/03

DIV : SRRD

BRAN: PRB

SECT: IO

REVR :

CONTR:

NEGOT DATE: / /

PROJ DATE: / /

2/10/03

* * * DATA REVIEW INSTRUCTIONS * * *

Please complete the 8 month acute toxicity review for this product.

Attached:

81-1 thru 81-6 - MRID's 458404-02 thru -07

Thanks,
Venus

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
288085	PRB/IO	01/30/03	04/30/03	Y	Y	Y

100-02-150
4742-94-5

DATE OUT: 13/FEB/03

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI [], MUP [], EUP [x]

BARCODE No.: D288085 EPA RECEIVED DATE: 01/16/03 Reg./File Symbol No.: 1381-170

PRODUCT NAME: Actellic 5E Insecticide

MRID: 458404-01

COMPANY NAME: Agrilience, Inc.

Active Code: 674

FROM: Maria Rivera Piansay, Chemist
Product Chemistry Team
PRB/SRRD (7508C)

Maria Rivera Piansay

*Maria revised
4.3.03 - when she determined
03.17 + 20 were still being
conducted.*

TO: Venus Eagle-Kunst, CRM
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

*call Steve Rogoduckin on 4.3.03
to inquire about status of studies*

INTRODUCTION:

With this submission, Agrilience, Inc. provided a CSF for the basic formulation dated 01/06/03, a draft label dated 01/16/03, product chemistry data (MRID number 458404-01) and a data matrix dated 01/13/03. The registrant is requesting FIFRA Section 4 reregistration of Actellic 5E Insecticide, EPA Reg. No. 1381-170.

An Interim Reregistration Eligibility Decision (IRED), Case number 2535, was issued in April 10, 2002 for the Technical Grade Active Ingredient (TGAI) Pirimiphos-Methyl: O-(2-(diethylamino)-6-methyl-4-pyrimidinyl)O,O-dimethyl phosphorothioate. The generic data base supporting the reregistration of Pirimiphos-methyl has been reviewed and found to be substantially complete.

FINDINGS:

1. The CSF for the basic formulation dated 01/06/03 is acceptable as presented. The nominal concentration of the active ingredient agrees with that on the label, meeting PR Notice 91-2. The certified limits on the active and the inert ingredients comply with the requirements of 40 CFR 158.175(b)(2). All ingredients listed on the CSF are cleared for use in the formulation of pesticides.
2. Except for the data gaps noted in Finding 3, all product chemistry data submitted in the Data Matrix and MRID number 458404-01 satisfy the Group A and Group B series guideline requirements which pertain to Product Identity, Composition and Analysis and Physical and Chemical Properties, respectively.
3. The registrant has indicated in the Data Matrix dated 01/13/03 that they are currently conducting the Storage Stability and Corrosion Characteristics studies for the subject product. Until the data are submitted for review, Storage Stability and Corrosion Characteristics are cited as data gaps.
4. The product chemistry aspects of the labeling are acceptable. The Ingredients statement, The Physical and Chemical Hazards statement and the Storage and Disposal statement are all acceptable as per 40 CFR 156.10(g), PR Notice 91-2, 40 CFR 156.10(h)(2)(iii) and 40 CFR 156.10(i)(2)(ix).

CONCLUSIONS:

Except for Storage Stability and Corrosion Characteristics, the registrant has satisfied product chemistry data requirements for the reregistration of Actellic 5E Insecticide, EPA Reg. No. 1381-170.

REVIEW OF PRODUCT CHEMISTRY DATA:**PRODUCT NAME:** Actellic 5E Insecticide**EPA Reg. No:** 1381-170**Group A: Series 830-Product Identity, Composition, and Analysis (40 CFR158.155, .160, .165, .167, .170, .175 & .180).****830-1550 Product Identity and Composition**

This product is produced by a non-integrated formulation system using a registered active ingredient source Pirimiphos-methyl Technical, EPA Reg. No. 1381-171, and has a label claim nominal concentration of 57% pirimiphos-methyl, with 43% other ingredients.

830-1600 Description of Materials Used to Produce the Product

Refer to Confidential Appendix A.

830-1620 Discussion of Formulation Process

Refer to Confidential Appendix A.

830-1670 Discussion of Formation of Impurities

Refer to Confidential Appendix A.

830-1700 Preliminary Analysis

Refer to Confidential Appendix A.

830-1750 Certified Limits

Refer to Confidential Appendix A.

830-1800 Enforcement of Analytical Method

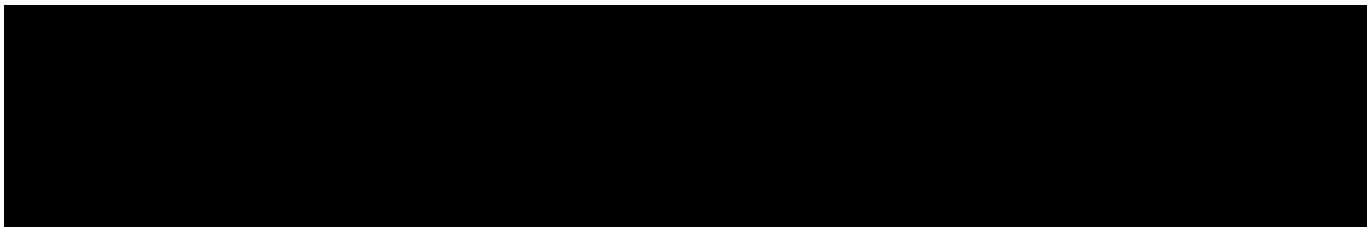
Methods of analysis for pirimiphos-methyl and its impurities have been previously reviewed and accepted in connection with reregistration for case number 2535. Pirimiphos-methyl may be determined by Gas-liquid chromatography, Agrilliance method "Determination of Pirimiphos-Methyl by Internal Standard Gas Liquid Chromatography" (MRID number 458404-01). The octadecane internal standard (dissolved in methylene chloride) is added to pirimiphos-methyl samples. 1 μ L aliquot is injected into a gas chromatograph equipped with a flame ionization detector, and the areas of the peaks obtained at the retention times of octadecane and pyrimiphos-methyl are measured with a computing integrator. These areas are used to calculate the pirimiphos-methyl content of the samples based upon a response factor obtained using known amounts of pure pirimiphos-methyl and octadecane. Sample calculations were included. This method has been previously validated and is determined to be adequate in the determination of pirimiphos-methyl in pesticide samples.

Group B: Series 830- Physical and Chemical Properties (40 CFR 158.190): MRID No.: Data Matrix dated 01/13/03

GUIDELINE REFERENCE NO. (GRN)/ TITLE 830	VALUE OR QUALITATIVE DESCRIPTION/ METHOD(S) USED WHERE APPLICABLE AND REFERENCES
-6302 Color	Amber
-6303 Physical State	Liquid
-6304 Odor	Petroleum solvent
-6314 Oxidation/Reduction: Chemical Incompatibility	"N/A - Product does not contain an oxidizing or reducing agent or functional group of significant reactivity."
-6315 Flammability/Flame Extension	149.5°F (65.3°C)
-6316 Explodability	"N/A"
-6317 Storage Stability	"A one year storage stability is being conducted." (Data gap)
-6319 Miscibility	Not applicable; product is not labeled to be diluted with petroleum solvents.
-6320 Corrosion Characteristics	"To be determined by storage stability study conducted in commercial packaging. None expected. (Data gap)"
-6321 Dielectric Breakdown Voltage	"N/A - Product not intended for use around electrical equipment."
-7000 pH	5.84 - 1% aqueous solution
-7100 Viscosity	14.347 @ 20°C; 6.940 @ 40°C
-7300 Density/Relative Density/Bulk Density	Specific gravity - 1.04

Confidential Appendix A830-1600 Description of Materials Used to Produce the Product

The materials used in the formulation of this product are listed in the CSF dated 01/06/03.

830-1650 Description of Production Process830-1670 Discussion of Formation of Impurities

"No impurities other than those typically present in the technical grade active ingredient can reasonably be expected. The manufacturing process for production of the end-use product does not involve any chemical reactions nor is it produced by an integrated formulation system. Based on the results of exploratory chemical stability testing there is no indication of any post-production reactions."

830-1700 Preliminary Analysis

Not required for products produced by a non-integrated system.

830-1750 Certified Limits

Pirimiphos-Methyl: Lower Limit: 55.29%; Nominal Conc.: 57.00%; Upper Limit: 58.71%

M.R. Piansay and Central File (EPA Reg. No. 1381-170)
7508C:SRRD:PRB:CM-2: M.R.P.: (13/FEB/03):703-308-8063:<1381-170>

THIS REVIEW CONTAINS FIFRA CBI

Manufacturing process information may be entitled to confidential treatment

DP BARCODE: D288085

CASE: 018282
SUBMISSION: S628359

DATA PACKAGE RECORD
BEAN SHEET

DATE: 01/30/03
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 674 8 MNTH RESP-PROD SPC DATA
RANKING : 10 POINTS ()
CHEMICALS: 108102 Pirimiphos-methyl (ANSI) 57.0000%
ID#: 001381-00170 ACTELIC 5E INSECTICIDE
COMPANY: 001381 AGRILIANCE, LLC
PRODUCT MANAGER: 04 MEREDITH LAWS 703-308-9366 ROOM: CM2 282
PM TEAM REVIEWER: VENUS EAGLE-KUNST 703-308-8045 ROOM: CM2 117 M
RECEIVED DATE: 01/16/03 DUE OUT DATE: 07/15/03

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 288085 EXPEDITE: N DATE SENT: 01/30/03 DATE RET.: / /
CHEMICAL: 108102 Pirimiphos-methyl (ANSI)
DP TYPE: 001 Submission Related Data Package
CSF: Y LABEL: Y

ASSIGNED TO	DATE	IN	DATE	OUT	ADMIN DUE DATE: 04/30/03
DIV : SRRD	/	/	/	/	NEGOT DATE: / /
BRAN: PRB	/	/	/	/	PROJ DATE: / /
SECT: IO	/	/	/	/	
REVR :	/	/	/	/	
CONTR:	/	/	/	/	

* * * DATA REVIEW INSTRUCTIONS * * *

Please complete the 8 month product chemistry review for this product.

Attached:
61,62,63 series info - MRID 45840401

Thanks,
Venus

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1 hour per response for registration activities and 1 hour per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

SUMMARY OF THE PHYSICAL/CHEMICAL PROPERTIES (PR Notice 98-1)

1. PRODUCT NAME: Actellic 5E Insecticide		2. Reg. No. 1381-170
3. COMPANY NAME: Agrilience, LLC		4. SUBMISSION DATE: Jan. 13, 2003
5. FIRST SUBMISSION [X]	7. PESTICIDE TYPE: Insecticide	10. REGISTRATION []
6. RESUBMISSION []		11. REREGISTRATION [X].
8. FORMULATED MANUFACTURING-USE PRODUCT [] or 9. END-USE PRODUCT [X]		12. REREG CASE # 2535
13. PRODUCT MANAGER OR CHEMICAL REVIEW MANAGER #/NAME (IF KNOWN): Joanne Edwards		16. MRID or REPORT NO.
14. GUIDELINE REFERENCE NO. (GRN)/TITLE	15. VALUE or QUALITATIVE DESCRIPTION/METHOD(s) USED WHERE APPLICABLE AND REFERENCES	

Group B, Series 830-Physical and Chemical Properties (40 CFR 158.190)

-6302 Color	Amber	
-6303 Physical State	Liquid	
-6304 Odor	Petroleum Solvent	
-6314 Oxidation/Reduction: Chemical Incompatibility	N/A - Product does not contain an oxidizing or reducing agent or functional group of significant reactivity.	
-6315 Flammability/Flame Extension	149.5° F (65.3° C) Pensky-Martens Closed Cup (ASTM D93)	
-6316 Explodability	N/A	
-6317 Storage Stability	A one year storage stability is being conducted.	
-6319 Miscibility	100% Dispersible in Water	
-6320 Corrosion Characteristics	To be determined by storage stability study conducted in commercial packaging. None expected.	•••••
-6321 Dielectric Breakdown Voltage	N/A - Product not intended for use around electrical equipment.	•••••
-7000 pH	5.84 - a 1% solution in water using a pH meter	•••••
-7100 Viscosity	14.347 @ 20° C 6.940 @ 40° C ASTM D445 Test Method	•••••
-7300 Density/Relative Density/ Bulk Density	Specific Gravity = 1.04	•••••

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.

Do not send completed form to this address.

SELF-CERTIFICATION STATEMENT FOR THE PHYSICAL/CHEMICAL PROPERTIES (PR NOTICE 98-1)

Product Name:

Actellic 5E Insecticide

Reg. No./File Symbol No. 1381-170

(if known) or Company No.

SELF-CERTIFICATION STATEMENT:

I certify that the reported information on the "Summary Form" represents a true and accurate record of the test results of studies generated or owned by (Company Name): AgriLiance, LLC and that the values of the properties reported are reliable. I further certify that such data was generated in substantial conformity with OPPTS Test Guidelines Series 830 Product Properties, applicable to my product, and in effect at the time of submission.

As a condition of registration, EPA may, by order, (1) withdraw a pending registration, (2) suspend the registration of this product without opportunity for hearing, or (3) assess civil penalties provided for in section 14 of FIFRA for violations of section 12(a)(2)(N) of FIFRA without opportunity for hearing, if I have not submitted to EPA within thirty (30) days of receipt of a request by the Agency, or within a specified time agreed to by the Agency, test results of studies summarized in the "Summary Form."

As a condition of registration, EPA may, by order, (1) withdraw a pending registration, (2) suspend the registration of this product without opportunity for hearing, or (3) assess civil penalties provided for in section 14 of FIFRA for violations of sections 12(a)(2)(N), 12(a)(2)(R) of FIFRA without opportunity for hearing, if I fail to provide to EPA within thirty (30) days of receipt of a notification of error, or within a specified time agreed to by the Agency, information that EPA determines is required to correct the error.

Type Applicant's Name:

Steven E. Rogosheske

Title: Manager, Product Registration

Telephone No.

(651) 451-5409

Applicant's Signature



Date:

1-13-03



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 3, 2003

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

AGRILIANCE, LLC
PO Box 64089
ST. PAUL, MN 55164-0089

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 10-NOV-03. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Alice Walker, Ph.D.

REGULATORY CONSULTING • 481 COUNTRY CLUB DRIVE • SENATOBIA, MS 38668

461180-00

FEDERAL EXPRESS

November 6, 2003

Document Processing Desk (DCI)
Office of Pesticide Programs (7508C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attn: Ms. Venus Eagle, Product Specific DCI Manager
Special Review and Reregistration Division

RE: Pirimiphos-Methyl, Case No. 1381, Chemical No. 0108102
Actellic 5E Insecticide, EPA Reg. No. 1381-170
Submission of Storage Stability and Corrosion Characteristics in Response to Product
Specific DCI

I have been authorized by AGRILIANCE, LLC to act on its behalf regarding subject submission.
Correspondence confirming my appointment was submitted to you last month.

I am enclosing the following report, in triplicate, in support of the continued registration of
Actellic 5E Insecticide:

46118001 Storage Stability (OPPTS 830.6317) and Corrosion Characteristics (OPPTS 830.6320)

Based on the results of this study, Actellic 5E Insecticide appears to be stable and non-corrosive.

With the submission of this study, I believe that AGRILIANCE has now satisfied all the product
chemistry, as well as the acute toxicology requirements, of the product specific data call-in
affecting this registration. We are anxious to have this study reviewed and to close the file on
this DCI.

If you have any questions, please do not hesitate to call.

Sincerely,



Alice Walker, Ph.D.
Regulatory Agent for
AGRILIANCE, LLC

/s

Enclosures

cc: Nathan Wright

Alice Walker, Ph.D.

REGULATORY CONSULTING • 481 COUNTRY CLUB DRIVE • SENATOBIA, MS 38668

461180-00

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Special Review and Reregistration Division

RE: Pirimiphos-Methyl, Case No. 1381, Chemical No. 0108102
Actellic 5E Insecticide, EPA Reg. No. 1381-170
Submission of Storage Stability and Corrosion Characteristics in Response to Product
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affecting this registration. We are anxious to have this study reviewed and to close the file on
this DCI.

If you have any questions, please do not hesitate to call.

Sincerely,



Alice Walker, Ph.D.
Regulatory Agent for
AGRILIANCE, LLC

/s
Enclosures
cc: Nathan Wright

Administrative

Materials



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 1381-170	2. EPA Product Manager George Tompkins	3. Proposed Classification <input type="checkbox"/> None <input checked="" type="checkbox"/> Restricted
4. Company/Product (Name) Actellic 5E Insecticide	PM#	
5. Name and Address of Applicant (Include ZIP Code) Agrilience, LLC, c/o Alice Walker Consulting 481 Country Club Drive Senatobia, MS 38668 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of corrosion characteristics and storage stability in response to product-specific DCI.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
Certification must submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Alice Walker, Ph.D.	Title Agent	Telephone No. (Include Area Code) 662-562-5995
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped) 54
2. Signature <i>Alice Walker</i>	3. Title Agent	
4. Typed Name Alice Walker, Ph.D.	5. Date November 6, 2003	

DATE OUT: 13/FEB/03

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI [], MUP [], EUP [x]

BARCODE No.: D288085 EPA RECEIVED DATE: 01/16/03 Reg./File Symbol No.: 1381-170

PRODUCT NAME: Actellic 5E Insecticide MRIDs: 458404-01

COMPANY NAME: Agrilliance, Inc. Action Code: 674

FROM: Maria Rivera Piansay, Chemist
Product Chemistry Team
PRB/SRRD (7508C)

Maria Rivera Piansay

TO: Venus Eagle-Kunst, CRM
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

INTRODUCTION:

With this submission, Agrilliance, Inc. provided a CSF for the basic formulation dated 01/06/03, a draft label dated 01/16/03, product chemistry data (MRID number 458404-01) and a data matrix dated 01/13/03. The registrant is requesting FIFRA Section 4 reregistration of **Actellic 5E Insecticide**, EPA Reg. No. **1381-170**.

An Interim Reregistration Eligibility Decision (IRED), Case number 2535, was issued in April 10, 2002 for the Technical Grade Active Ingredient (TGAI) Pirimiphos-Methyl: O-(2-(diethylamino)-6-methyl-4-pyrimidinyl)O,O-dimethyl phosphorothioate. The generic data base supporting the reregistration of Pirimiphos-methyl has been reviewed and found to be substantially complete.

FINDINGS:

1. The CSF for the basic formulation dated 01/06/03 is acceptable as presented. The nominal concentration of the active ingredient agrees with that on the label, meeting PR Notice 91-2. The certified limits on the active and the inert ingredients comply with the requirements of 40 CFR 158.175(b)(2). All ingredients listed on the CSF are cleared for use in the formulation of pesticides.
2. All data submitted in MRID number 458404-01 are acceptable and satisfy the Group A and Group B series guideline requirements which pertain to Product Identity, Composition and Analysis and Physical and Chemical Properties, respectively.
3. The product chemistry aspects of the labeling are acceptable. The Ingredients statement, The Physical and Chemical Hazards statement and the Storage and Disposal statement are all acceptable as per 40 CFR 156.10(g), PR Notice 91-2, 40 CFR 156.10(h)(2)(iii) and 40 CFR 156.10(i)(2)(ix).

CONCLUSIONS:

The registrant has satisfied product chemistry data requirements for the reregistration of **Actellic 5E Insecticide**, EPA Reg. No. **1381-170**.

REVIEW OF PRODUCT CHEMISTRY DATA:**PRODUCT NAME:** Actellic 5E Insecticide**EPA Reg. No:** 1381-170**Group A: Series 830-Product Identity, Composition, and Analysis (40 CFR158.155, .160, .165, .167, .170, .175 & .180).****830-1550 Product Identity and Composition**

This product is produced by a non-integrated formulation system using a registered active ingredient source Pirimiphos-methyl Technical, EPA Reg. No. 1381-171, and has a label claim nominal concentration of 57% pirimiphos-methyl, with 43% other ingredients.

830-1600 Description of Materials Used to Produce the Product

Refer to Confidential Appendix A.

830-1620 Discussion of Formulation Process

Refer to Confidential Appendix A.

830-1670 Discussion of Formation of Impurities

Refer to Confidential Appendix A.

830-1700 Preliminary Analysis

Refer to Confidential Appendix A

830-1750 Certified Limits

Refer to Confidential Appendix A.

830-1800 Enforcement of Analytical Method

Methods of analysis for pirimiphos-methyl and its impurities have been previously reviewed and accepted in connection with reregistration for case number 2535. Pirimiphos-methyl may be determined by Gas-liquid chromatography, Agrilliance method "Determination of Pirimiphos-Methyl by Internal Standard Gas Liquid Chromatography" (MRID number 458404-01). The octadecane internal standard (dissolved in methylene chloride) is added to pirimiphos-methyl samples. 1 μ L aliquot is injected into a gas chromatograph equipped with a flame ionization detector, and the areas of the peaks obtained at the retention times of octadecane and pyrimiphos-methyl are measured with a computing integrator. These areas are used to calculate the pirimiphos-methyl content of the samples based upon a response factor obtained using known amounts of pure pirimiphos-methyl and octadecane. Sample calculations were included. This method has been previously validated and is determined to be adequate in the determination of pirimiphos-methyl in pesticide samples.

Group B: Series 830- Physical and Chemical Properties (40 CFR 158.190): MRID No.: Data Matrix dated 01/13/03

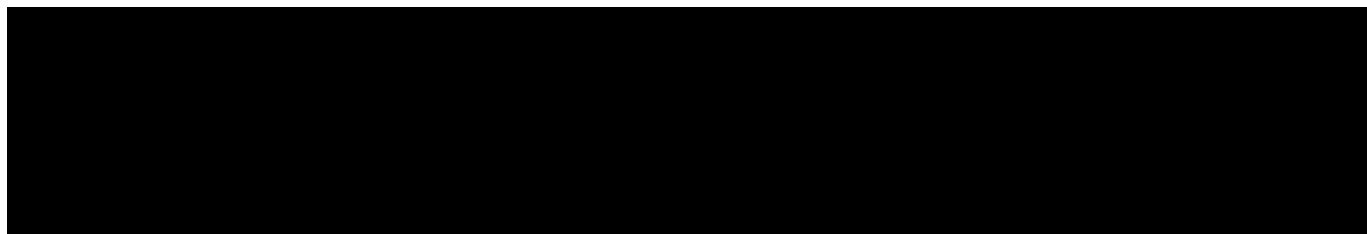
GUIDELINE REFERENCE NO. (GRN)/ TITLE 830	VALUE OR QUALITATIVE DESCRIPTION/ METHOD(S) USED WHERE APPLICABLE AND REFERENCES
-6302 Color	Amber
-6303 Physical State	Liquid
-6304 Odor	Petroleum solvent
-6314 Oxidation/Reduction: Chemical Incompatibility	"N/A - Product does not contain an oxidizing or reducing agent or functional group of significant reactivity."
-6315 Flammability/Flame Extension	149.5°F (65.3°C)
-6316 Explodability	"N/A"
-6317 Storage Stability	"A one year storage stability is being conducted." (Data gap)
-6319 Miscibility	Not applicable; product is not labeled to be diluted with petroleum solvents.
-6320 Corrosion Characteristics	"To be determined by storage stability study conducted in commercial packaging. None expected. (Data gap)"
-6321 Dielectric Breakdown Voltage	"N/A - Product not intended for use around electrical equipment."
-7000 pH	5.84 - 1% aqueous solution
-7100 Viscosity	14.347 @ 20°C; 6.940 @ 40°C
-7300 Density/Relative Density/Bulk Density	Specific gravity - 1.04

Confidential Appendix A

830-1600 Description of Materials Used to Produce the Product

The materials used in the formulation of this product are listed in the CSF dated 01/06/03.

830-1650 Description of Production Process



830-1670 Discussion of Formation of Impurities

"No impurities other than those typically present in the technical grade active ingredient can reasonably be expected. The manufacturing process for production of the end-use product does not involve any chemical reactions nor is it produced by an integrated formulation system. Based on the results of exploratory chemical stability testing there is no indication of any post-production reactions."

830-1700 Preliminary Analysis

Not required for products produced by a non-integrated system.

830-1750 Certified Limits

Pirimiphos-Methyl: Lower Limit: 55.29%; Nominal Conc.: 57.00%; Upper Limit: 58.71%

M.R. Piansay and Central File (EPA Reg. No. 1381-170)
7508C:SRRD:PRB:CM-2: M.R.P.: (13/FEB/03):703-308-8063:<1381-170>

THIS REVIEW CONTAINS FIFRA CBI

DATE OUT: 31/DEC/03

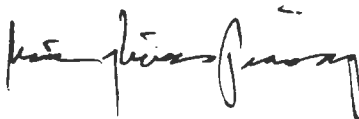
SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI []; MUP [x]; EUP []

BARCODE No.: 296750 EPA RECEIVED DATE: 11/10/03 Reg./File Symbol No.: 1381-170

PRODUCT NAME: Actellic 5E Insecticide MRID No.: 461180-01

COMPANY NAME: Agrilience, Inc. Action Code: 675

FROM: Maria Rivera Piansay, Chemist
Product Chemistry Team
PRB/SRRD (7508C)



TO: Venus Eagle-Kunst, CRM
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

INTRODUCTION:

In response to a previous product chemistry review by PRB/SRRD (M. Piansay, 02/13/03), the registrant submitted additional product chemistry data in support of the FIFRA Section 4 reregistration of **Actellic 5E Insecticide**, EPA Reg. No. **1381-170**.

FINDINGS:

In the previous review, Storage Stability and Corrosion Characteristics were cited as data gaps. The currently submitted MRID number 461180-01 contains acceptable data on Storage Stability and Corrosion Characteristics. In this study, two samples of the product were packaged in 28 ounce HDPE containers and put into storage for one year (at ambient laboratory conditions) following an initial analysis of the active ingredient. The percentage of Pirimiphos-methyl was determined in both samples by GLC at 3, 6, 9 and 12 months of storage. A reference standard was used to generate a calibration curve and linearity, accuracy, precision and recovery were also evaluated to ensure performance of the method. Visual examination of the containers were conducted after 12 months of storage. The results of the study are as follows:

Time	Pirimiphos-methyl Mean \pm SD ((%)
Initial	58.3 \pm 0.31
3 months	57.3 \pm 0.60
6 months	57.8 \pm 1.18
9 months	58.2 \pm 0.27
12 months	58.2 \pm 0.29

No physical changes to the test substance and its containers were observed throughout the one-year study period.

CONCLUSIONS:

The submitted data on Storage Stability and Corrosion Characteristics of the product are acceptable and the registrant has now satisfied the product chemistry data requirements for the reregistration of EPA Reg. No. **1381-170**.

DATE OUT: 31/DEC/03

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI []; MUP [x]; EUP []

BARCODE No.: 296750 EPA RECEIVED DATE: 11/10/03 Reg./File Symbol No.: 1381-170

PRODUCT NAME: Actellic 5E Insecticide MRID No.: 461180-01

COMPANY NAME: Agrilience, Inc. Action Code: 675

FROM: Maria Rivera Piansay, Chemist
Product Chemistry Team
PRB/SRRD (7508C)



TO: Venus Eagle-Kunst, CRM
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

INTRODUCTION:

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**Administrative
Materials**



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 1381-170	2. EPA Product Manager Joanne Edwards	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) AgriSolutions Actellic 5E Insecticide	PM # 14	
5. Name and Address of Applicant (Include ZIP Code) Agrilience, LLC P.O. Box 64089 St. Paul, MN 55164-0089 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Application for Reregistration in response to RED

Section - III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 28, 64 oz., 1 and 15 gallon		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input checked="" type="checkbox"/> Other <u>Stick-on-booklet</u>			

Section - IV

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Steve Rogosheske	Title Manager, Product Registration	Telephone No. (Include Area Code) 1 (631) 451-5409
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Manager, Product Registration	
5. Typed Name Steven E. Rogosheske	5. Date January 13, 2003	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Agrilience, LLC P.O. Box 64089, St. Paul, MN 55164-0089 (651) 451-5409	EPA Registration Number/File Symbol 1381-170
Active Ingredient(s) and/or representative test compound(s) Pirimiphos-methyl	Date Jan. 14, 2003
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food	Product Name Actellic 5E Insecticide

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulators Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method. or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Steven E. Rogosheske

Date

Jan. 14, 2003

Typed or Printed Name and Title

Steven E. Rogosheske - Mgr. Product Registration



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspects of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX



Date Jan. 13, 2003			EPA Reg No./File Symbol 1381-170		Page 1 of 1
Applicant's/Registrant's Name & Address Agriliance, LLC, P.O. Box 64089, St. Paul, MN 55164-0089			Product AgriSolutions Actellic 5E Insecticide		
Ingredient					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550 - 830.1800	Group A Product Chemistry		Agriliance	OWN	
81-1	Acute Oral Toxicity		Agriliance	OWN	
81-2	Acute Dermal Toxicity		Agriliance	OWN	
81-3	Acute Inhalation Toxicity		Agriliance	OWN	
81-4	Primary Eye Irritation		Agriliance	OWN	
81-5	Primary Skin Irritation		Agriliance	OWN	
81-6	Dermal Sensitization		Agriliance	OWN	
Signature 			Name and Title Steve Rogosheske - Manager, Product Registration		Date Jan. 13, 2003




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 204660

Form Approved OMB No. 2070-0060

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Ingredient					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Agriliance	OWN	
			Agriliance	OWN	
			Agriliance	OWN	
			Agriliance	OWN	
			Agriliance	OWN	
			Agriliance	OWN	
			Agriliance	OWN	
Signature 			Name and Title Steve Rogosheske - Manager, Product Registration		Date Jan. 13, 2003



ACTELIC[®] 5E INSECTICIDE

FOR CONTROL OF INSECTS ON STORED CORN AND GRAIN SORGHUM
(Including Bulk or Bagged Seed)

ACTIVE INGREDIENT:

Pirimiphos-methyl

0-(2-(diethylamino)-6-methyl-4-pyrimidinyl)0,0-dimethyl phosphorothioate 57%

OTHER INGREDIENTS: 43%

TOTAL 100%

ACTELIC 5E INSECTICIDE contains 5 pounds active ingredient per gallon.

KEEP OUT OF REACH OF CHILDREN DANGER

FIRST AID

- | | |
|-------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| If in eyes | <ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. |
| If swallowed | <ul style="list-style-type: none">• Call a poison control center or doctor for treatment advice.• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor. |
| If on skin or clothing | <ul style="list-style-type: none">• Do not give anything by mouth to an unconscious person.• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice. |
| If inhaled | <ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice. |

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. **NOTE TO PHYSICIAN:** Inducing vomiting as first aid for this substance may result in increased risk of chemical pneumonia or pulmonary edema caused by aspiration of the hydrocarbon solvent. Vomiting should be induced only under professional supervision. Atropine is antidotal for cholinesterase inhibition. Give 2 mg. of atropine intramuscularly or subcutaneously and repeat if symptoms of poisoning reappear. Pralidoxime (2 PAM) may be given if available. Give 1 gram intramuscularly or intravenously and repeat as necessary.

EPA Reg. No. 1381-170

Agrilience, LLC
P.O. Box 64089
St. Paul, MN 55164-0089

EPA Est. No. _____

Net Contents
Gals.
0/A13/2

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER**

Corrosive. Causes irreversible eye damage. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Personal Protective Equipment (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category G on the EPA chemical-resistant category selection chart.

Mixers, and loaders and other handlers supporting admixture seed and/or grain treatments must wear:

- Long sleeve shirt and long pants
- Shoes plus socks
- Chemical resistant gloves such as barrier laminate or Viton
- Protective eyewear

See engineering controls for additional requirements.

All other mixers, loaders, applicators and other handlers must wear:

- Coveralls over long sleeve shirt and long pants
- Chemical resistant footwear, plus socks
- Chemical resistant gloves such as barrier laminate or Viton
- Protective eyewear

In addition, mixers and loaders must wear

- Chemical resistant apron

USER SAFETY REQUIREMENTS

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent material that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

ENGINEERING CONTROLS

For all seed and/or grain treatments, handlers must use a closed mixing/loading system designed by the manufacturer to enclose the pesticide in a manner that prevents it from contacting handler. This product is formulated into a container designed for closed mixing and loading. In addition:

- Handlers must wear the PPE specified above for handlers supporting admixture seed and/or grain treatment.
- Handlers must have available to them in case of accident or spill: coveralls and chemical resistant footwear.

USER SAFETY RECOMMENDATIONS

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticides get inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of waste.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

PROHIBITIONS: Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

STORAGE: Store in a cool place and protect from freezing. If accidentally frozen, reconstitute by gently warming to room temperature and thoroughly mixing contents.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL:

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not enter treated areas or have contact with treated grain or seed until sprays have dried.

General Precautions and Restrictions

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Do not make more than one application per crop. Only treat corn or sorghum which has not previously been treated with any pirimiphos-methyl containing product.

[Containers 64 oz. or less] Do not use for admixture grain and seed treatments.

Do not allow this product to drift.

INSECTS CONTROLLED WITH ACTELIC 5E INSECTICIDE

COLEOPTERA

Cigarette beetle
Confused flour beetle
Corn sap beetle
Flat grain beetle
Granary weevil
Hairy fungus beetle

Maize weevil
Merchant grain beetle
Red flour beetle
Rice weevil
Sawtoothed beetle

LEPIDOPTERA

Almond moth
Angoumois grain moth
Indian meal moth

GENERAL REMARKS AND PRECAUTIONS

- Grains treated with Actellic 5E Insecticide at rates indicated on this label may be used immediately for any food or feed purpose.
- Do not store diluted Actellic 5E Insecticide in spray tank more than 48 hours before use.
- Calibrate spray equipment and periodically check in order to ensure proper spray rates.
- Avoid severely dusty application sites.
- Intended for storage insect control only. Not meant to be used for control of soil insects.

APPLICATION DIRECTIONS FOR GRAIN STORAGE

ADMIXTURE OR TOP DRESSING

(Only ONE application method may be used per load of stored corn, popcorn or sorghum grain)

The best practice to protect stored corn and grain sorghum from insect infestation is to use an admixture treatment of ACTELLIC 5E INSECTICIDE. However, as it may not always be possible to move grain, a surface treatment of ACTELLIC 5E INSECTICIDE will help control light existing infestation and prevent the establishment of migrating insects. The top dressing application will not substitute for a treatment of the entire amount of stored corn or grain sorghum. But within your current stored grain management system, it will help protect the surface from invasion by insects. If grain is already heavily infested prior to going into storage, fumigation should be used.

Notice: Either treatment should only be used if the corn or grain sorghum has not previously received an application of ACTELLIC 5E INSECTICIDE. To determine whether the crop has been previously treated call toll-free 1-800-677-6324 for a free analysis.

ADMIXTURE TREATMENT

Apply spray solution uniformly with suitable application equipment as grain enters storage or export containers. Select nozzle size and operating pressure to adjust the application rate with flow of grain. Prepare desired dilution of ACTELLIC 5E INSECTICIDE in spray tank and mix well. Make sure spray solution stays mixed, especially in large holding tanks. Apply the spray solution as a coarse, uniform low pressure spray in order to minimize drift. Shield nozzle if necessary. Apply the specified amount of Actellic 5E Insecticide in 5 gallons of water or 3-5 gallons of at least twice refined soybean oil to each 30 tons (60,000 pounds) of grain according to the following rates.

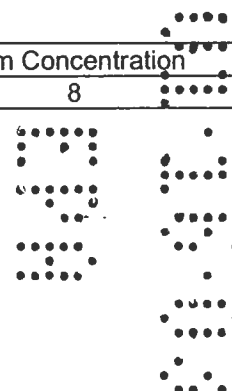
	Fluid Ounces	ppm Concentration
Shelled Corn (field corn, seed corn, popcorn)	9.2-12.3	6-8
Grain Sorghum	9.2-12.3	6-8
Grain	No. of Bushels Approximately Equal to 30 Tons of Grain	
Shelled Corn (field corn, seed corn, popcorn)	1,071	
Grain Sorghum	1,071	

TOP DRESSING TREATMENT

To each 1,000 square feet of grain surface, apply 3 fluid ounces of Actellic 5E Insecticide diluted in 2 gallons of water. The treatment should be split as follows: Spray half of the mixture evenly over the surface and rake into the grain to a depth of 4 inches. Apply the remaining half of the mixture to the raked surface.

Before making a surface application of Actellic 5E Insecticide, it will be necessary to remove any webbing and break up crusting that exists on the grain surface. If high numbers of Indian Meal Moth worms (2-3 per sq ft) exist, it will be best to remove the webbing, fumigate, and then apply ACTELLIC 5E INSECTICIDE as a surface application. Mix the following amount of Actellic 5E Insecticide with 2 gallons of water for a total mixture to treat 1,000 sq ft of grain surface:

	Fluid Ounces	ppm Concentration
Corn and Sorghum	3.0	8



APPLICATION DIRECTIONS FOR STORED BULK OR BAGGED SEED* (Corn, Popcorn & Sorghum)

***Commercial Use Only on Seed conditioned, dyed and sold only for the purpose of planting.**

ADMIXTURE TREATMENT

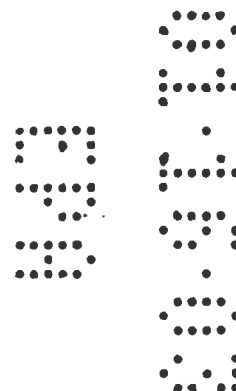
Apply spray solution uniformly with suitable application equipment as grain enters storage or final treatment. Select nozzle size and operating pressure to adjust the application rate with flow of grain. Prepare desired dilution of Actellic 5E Insecticide in spray tank and mix well. Make sure spray solution stays mixed, especially in large holding tanks. Apply the spray solution as a coarse, uniform low-pressure spray in enclosed systems only. Apply the specified amount of Actellic 5E Insecticide in 5 gallons of water or 3-5 gallons of at least twice refined soybean oil to each 30 tons (60,000 pounds) of grain according to the following rates.

	Fluid Ounces	ppm Concentration
Shelled Corn (field corn, seed corn, popcorn)	9.2-12.3	6-8
Grain Sorghum	9.2-12.3	6-8
Grain	No. of Bushels Approximately Equal to 30 Tons of Grain	
Shelled Corn (field corn, seed corn, popcorn)	1,071	
Grain Sorghum	1,071	

Notice of Warranty

Seller warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use. SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, NOR IS ANY REPRESENTATIVE OF SELLER AUTHORIZED TO MAKE ANY SUCH WARRANTY OR MODIFY THESE TERMS. This warranty does not extend to the storage, handling or use of this product contrary to label instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to Seller, and Buyer assumes the risk of any such storage, handling or use. Seller shall not be responsible for incidental or consequential damages, if any, resulting from a breach of warranty.

Actellic® is a registered trademark of Syngenta Crop Protection





July 22, 2002

Document Processing Desk (PDCI/PRB)
Ms. Venus Eagle
Office of Pesticide Programs (7508C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: Pirimiphos-methyl - IRED
Case No. 2535, Chemical No. 108102
Product Specific Data Call-In

Dear Ms. Eagle:

In response to the Data Call-In of the subject technical active ingredient, Agriliance, LLC is submitting the completed and signed Product Specific Data Call-In Response forms and the Requirements Status and Registrant's Response forms for the individual products containing the active ingredient.

Also enclosed is a request for time extension for some of the label changes require by the IRED for Pirimiphos-methyl. A copy of this request was sent to Ms. Lorilyn Montford as well.

If there are any questions regarding this submission, I can be reached at the number below or by FAX at (651) 451-5559, or E-mail, serogosheske@agriliance.com.

Sincerely,

Steve Rogosheske
Manager, Product Registration
(651) 451-5409

Enclosures



United States Environmental Protection Agency
Washington, D. C. 20460

DATA CALL-IN RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company name and Address AGRILIANCE, LLC BOX 64089 ST. PAUL MN 55164		2. Case # and Name 2535 Pirimiphos-methyl		3. Date and Type of DCI PRODUCT SPECIFIC	
4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
1381-170		N.A.	N.A.		X
8. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law. Signature and Title of Company's Authorized Representative <i>Steven Rogosheske</i> <i>Manager, Product Registration</i>				9. Date <i>July 22, 2002</i>	
10. Name of Company Contact <i>Steven Rogosheske</i>				11. Phone Number <i>(651) 451-5409</i>	

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company name and Address
AGRILIANCE, LLC
BOX 64089
ST. PAUL MN 55164

2. Case # and Name
2535 Pirimiphos-methyl

EPA Reg. No. 1381-170

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 1381-RD-8482

4. Guideline
Requirement
Number

5. Study Title

PROTOCOL

Progress
Reports

1 2 3

6. Use
Pattern

7. Test
Substance

8. Time
Frame

9. Registrant
Response

Prod Chem - Regular Chemical

830.1550	Product identity & composition (1)				ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
830.1600	Description of materials used (1,2) to produce the product				ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
830.1620	Description of production (1,2) process				ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
830.1650	Description of formulation (1,2) process				ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
830.1670	Discussion of formation of (1,3) impurities				ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
830.1700	Preliminary analysis (1,4)				ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
830.1750	Certified limits (1,5)				ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
830.1800	Enforcement analytical method (1)				ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
830.6302	• Color ••• (17)				ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
830.6303	• Physical state •••				ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
830.6304	• Odor ••• (17)				ABCDEFGHIJKLMNO	MP/EP	8 mos.	/

10. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete.
I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment
or both under applicable law.

Signature and Title of Company's Authorized Representative

Steven Rogosheske Manager, Product Registration

11. Date

July 22, 2002

12. Name of Company Contact

Steven Rogosheske

13. Phone Number

(651-451-5409)

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company name and Address
AGRILIANCE, LLC
BOX 64089
ST. PAUL MN 55164

2. Case # and Name
2535 Pirimiphos-methyl

EPA Reg. No. 1381-170

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 1381-RD-8482

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
			1	2	3				
830.7000	pH (9)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
830.7050	UV/Visible absorption					ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
830.7100	Viscosity (13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
830.7300	Density					ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
830.6314	Oxidation/reduction: chemical (10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
	incompatibility								
830.6315	Flammability (11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
830.6316	Explodeability (12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
830.6317	Storage stability					ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
830.6319	Miscibility (14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
830.6320	Corrosion characteristics					ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
830.6321	Dielectric breakdown voltage (15)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
	<u>Acute Toxic - Regular Chemical</u>								
870.1100	Acute oral toxicity (1,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
870.1200	Acute dermal toxicity (1,2,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
870.1300	Acute inhalation toxicity (3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
870.2400	Acute eye irritation (2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
870.2500	Acute dermal irritation (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	/
870.2600	Skin sensitization (4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	/

Initial to indicate certification as to information on this page
(full text of certification is on page one).

SR

Date

July 22, 2002

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 2535 Pirimiphos-methyl

Key: MP = manufacturing-use product; EP = end-use product; provided formulators purchase their active ingredient(s) from a registered source, they need not submit or cite data pertaining to the purchased product. [NOTE: If a product is a 100 percent repackage of another registered product, registrants are not subject to any data requirements identified in the tables.]; TEP = typical end-use product; TGA1 = technical grade of the active ingredient; PA1 = "pure" active ingredient; PAIRA = "pure" active ingredient, radiolabeled.

Use Categories Key:

A - Terrestrial food crop	B - Terrestrial food feed crop	C - Terrestrial nonfood crop	D - Aquatic food crop	E - Aquatic nonfood outdoor
F - Aquatic nonfood Industrial	G - Aquatic nonfood residential	H - Greenhouse food crop	I - Greenhouse nonfood crop	J - Forestry
K - Residential outdoor	L - Indoor food	M - Indoor nonfood	N - Indoor Medical	O - Indoor residential

Footnotes: [The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

Prod Chem - Regular Chemical

- 1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).
- 2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.
- 3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.
- 4 To support registration of an MP or EP, whether produced by an integrated system or not, the technical grade of Active Ingredient must be analyzed. If the technical grade of Active Ingredient cannot be isolated, a statement of composition of the practical equivalent of the technical grade of Active Ingredient must be submitted. Data on EPs or MPs will be required on a case-by-case basis.
- 5 Certified limits are not required for inert ingredients in products proposed for experimental use.
- 9 Required if test substances are dispersible with water.
- 10 Required if product contains an oxidizing or reducing agent.
- 11 Required if product contains combustible liquids.
- 12 Required if product is potentially explosive.
- 13 Required if product is a liquid.
- 14 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.
- 15 Required if end-use product is liquid and is to be used around electrical equipment.
- 17 Not required unless efficacy data are required.

Acute Toxic - Regular Chemical

- 1 Not required if test material is a gas or highly volatile.
- 2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.
- 3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
- 4 Required unless repeated dermal exposure does not occur under conditions of use.

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 2535 Pirimiphos-methyl

Footnotes (cont.):

- 37 Testing of the EP dilution in addition to the EP or MP is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

843

20-92-20



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

November 4, 2004

Agrilliance, LLC c/o Alice Walker
481 Country Club Drive
Senatobia, Mississippi 38668

Subject: Actellic 5E Insecticide
EPA Reg. No. 1381-170
Your Amendment Dated June 4, 2004

Dear Ms. Walker,

There is no objection to your request for an alternate formulation for the subject product. This information has been filed in the subject file. If you have any questions, please contact me at (703) 305-6736, or electronically at edwards.joanne@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Joanne S. Edwards".

Joanne S. Edwards, Entomologist
Insecticide-Rodenticide Branch
Registration Division (7505C)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OPPTS/OPP/RD/TRB/PRODUCT CHEMISTRY TEAM

WASHINGTON, D.C. 20460

DATE OUT: October 29, 2004

SUBJECT: Product Chemistry Review Of Acetellic 5E Insecticide
DP BARCODE No.: 308472
REG./File Symbol No.: 1381-170
DECISION: 345478
PC CODE: 108102
USE: Food Use

FROM: Linda L. Kutney, Chemist *Linda L. Kutney* *HP*
Product Chemistry Team *10/29/04* *10/29/04*
Technical Review Branch/RD (7505C)

TO: John Hebert, Joanne Edwards RM-7
Insecticide Rodenticide Branch/ RD (7505C)

INTRODUCTION:

Agriliance, LLC, Inc., has submitted a revised alternate CSF (dated 6/4/04) for their end-use product, Acetellic 5E Insecticide. The label claim for this product is 57.0% Pirimiphos-Methyl, and there are food uses. No data were submitted.

SUMMARY OF FINDINGS:

1. The current label was not submitted for review and is assumed to be acceptable.
2. All of the inert components used are acceptable for the proposed food uses.

TRB CONCLUSIONS:

The alternate CSF (dated 6/4/04) is acceptable.



Joanne Edwards

09/22/2004 01:14 PM

To: Alice Walker <alicewalker@epaconsulting.net>
cc: John Hebert/DC/USEPA/US, ,
cc: Joanne Edwards/DC/USEPA/US@EPA
Subject: Re: Actellic 5E, EPA Reg. No. 1381-170

Alice- I will print a copy of this email from you and attachment, pull the jacket for the subject product, get it assigned by John as incoming and put it into chemistry review. I am not sure what to tell you about chemistry turnaround times, since this is a non-fast track.

John- anything else to add?

Joanne Edwards
EPA/OPPTS/OPP/RD/IRB
(703) 305-6736
edwards.joanne@epa.gov
Alice Walker <alicewalker@epaconsulting.net>



Alice Walker
<alicewalker@epaconsulting.net>

09/22/2004 11:53 AM

To: Joanne Edwards/DC/USEPA/US@EPA
cc:
Subject: Actellic 5E, EPA Reg. No. 1381-170

Dear Joanne,

See attached file on [REDACTED] This information was sent to Kerry Leifer on June 1, 2004.

Let me know what else needs to be done to get approval of alternate CSF for Actellic 5E.

Alice





Alice Walker
<alicewalker@epacon
sulting.net>

09/21/2004 01:11 PM

To: Joanne Edwards/DC/USEPA/US@EPA
cc: gchalvorson@agriliance.com
Subject: Actellic 5E Insecticide, 1381-170

Hi, Joanne,

Please reference your email below re an alternate CSF for subject registration. You requested 100% composition of new inert, [REDACTED]. I've just spoken with [REDACTED] with [REDACTED] and he said the information was sent to you a couple of months ago. Did you receive it? Agriliance is anxious to get approval of this alternate CSF. Can you give me an idea when you might get to it?

Thanks,
Alice

Edwards.Joanne@epamail.epa.gov wrote:

Alice- I pulled your jackets (to file letter of authorization), and looked at what you were doing on the revised CFS. I talked with one of our chemists, you looked up the replacement you added. There is no code, which means this is not cleared. I asked what you would need, and was told you need to provide a Material Data Safety Sheet which has the following information (the one you sent didn't have this information):
chemical composition
chemical name
CAS number
% of each components.

We need this to further process. Please let me know if you would like a "formal" written letter in this regard, or if you can just resubmit with the info needed to "clear" the inert you now list.

Joanne Edwards
EPA/OPPTS/OPP/RD/IRB
(703) 305-6736
edwards.joanne@epa.gov

Alice Walker, Ph.D.

REGULATORY CONSULTING • 481 COUNTRY CLUB DRIVE • SENATOBIA, MS 38668

VIA CERTIFIED MAIL

June 8, 2004

Document Processing Desk (Amnd)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

Attn: John Hebert

Re: Actellic 5E Insecticide
(EPA Reg. No. 1381-170)
Amendment to Add an Alternate CSF

Dear Mr. Hebert:

Enclosed is an alternate Confidential Statement of Formula for Actellic 5E Insecticide. We wish to [REDACTED] to replace the existing inert system as needed. We are including an MSDS for the alternate inert as well as EPA Form 8570-1, Application for Pesticide form.

Thank you for your assistance.

Sincerely,

Alice Walker

Alice Walker, Ph.D.
Agent for
AGRILIANCE, LLC

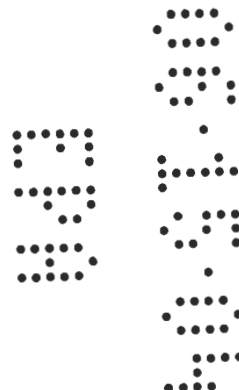
/s

Enclosures

cc: Mr. Gary Halvorson

Phone 662-562-5995 • Fax 662-560-5391
Email alicewalker@epaconsulting.net

Inert ingredient information may be entitled to confidential treatment





United States
Environmental Protection Agency
Washington, DC 20460

	Registration
✓	Amendment
	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 1381-170	2. EPA Product Manager John Hebert	3. Proposed Classification <input checked="checked" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Actellic 5E Insecticide	PM# 7	
5. Name and Address of Applicant <i>(Include ZIP Code)</i> Agrilliance, LLC c/o Alice Walker 481 Country Club Drive Senatobia, Mississippi 38668 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

☒ Amendment - Explain below.

☐ Resubmission in response to Agency letter dated _____

☐ Notification - Explain below.

☐ Final printed labels in response to Agency letter dated _____

☐ "Me Too" Application.

☐ Other - Explain below.


Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Alternate CSF substituting [REDACTED] for the existing inert system

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt No. per container	
3. Location of Net Contents Information 4. Size(s) Retail Container 5. Location of Label Directions			
<input type="checkbox"/> Label <input type="checkbox"/> Container		<input type="checkbox"/> _____	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____	

Section - IV

1. Contact Point <i>(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)</i>		
Name ALICE WALKER, Ph.D	Title Regulatory Consultant	Telephone No. (Include Area Code) 602-562-5995
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Consultant	
4. Typed Name ALICE WALKER, PhD	5. Date 6.04.04	

Inert ingredient information may be entitled to confidential treatment

CR#:

04-0471

REQUESTOR NAME:

LINDA L. KUTNEY

LINDA KUTNEY

REQUEST DATE:

10/13/04

TEL

305-7382

ORG

TRB

ROOM

270

MAIL CODE

7505C

(Division Branch)

CSF ATTACHED:

☒

YES IF CSF is attached complete Item A and the chemical name in Item B

☐

NO IF CSF is not attached complete Item A through Item C

A. INFORMATION REQUIRED:

✓ Check Applicable Category

☒

Provide PCC and Tolerance Exemption Status for Food-Use Inert Ingredient(s)

☐

Provide PCC for Non-Food Use Inert Ingredient(s)

☐

Provide PCC for Active Ingredient(s)

☐

Provide PCC for Dye

☐

Determine if Fragrance is Acceptable for Use in Formulation

☐

Other (Describe):

IS MSDS INCLUDED?

YES

+ SO IS CSF

B. INGREDIENT INFORMATION:

OF INERT

Ingredient No. 1:

Ingredient No. 2:

Chem Name

Chem Name

Trade Name

Trade Name

CAS Reg. No.

CAS Reg. No.

Ingredient No. 3:

Ingredient No. 4:

Chem. Name

Chem. Name

Trade Name

Trade Name

CAS Reg. No.

CAS Reg. No.

C. PESTICIDE PRODUCT INFORMATION

EPA Reg. No./File Symbol:

1381-170

Product Name

Actellic SE Insecticide

Registrant:

Agrilience LLC

Food-Use Pesticide

☒

Yes

☐

No

Percent in Formulation (For Fragrances/Dyes only)

%

INFORMATION REPORTED:

Ingredient No. 1:

Ingredient No. 2:

PCC:

PCC:

Tol. Status/Other Info

40CFR180.920

Tol. Status/Other Info:

Ingredient No. 3:

Ingredient No. 4:

PCC:

PCC:

Tol. Status/Other Info:

Tol. Status/Other Info:

Completed by:

LINDA

FAN

Date Completed:

10/13/2004

Once completed, this form may be entitled to treatment as CBI under section 10 of FIFRA. If so, a red CBI cover should be affixed to the request form and the document handled accordingly.

Inert ingredient information may be entitled to confidential treatment

 **Joanne Edwards**

To: alicewalker@epaconsulting.net

cc:

07/20/2004 03:27 PM

Subject: revised CSF

Alice- I pulled your jackets (to file letter of authorization), and looked at what you were doing on the revised CFS. I talked with one of our chemists, you looked up the replacement you added. There is no code, which means this is not cleared. I asked what you would need, and was told you need to provide a Material Data Safety Sheet which has the following information (the one you sent didn't have this information):

chemical composition

chemical name

CAS number

% of each components.

We need this to further process. Please let me know if you would like a "formal" written letter in this regard, or if you can just resubmit with the info needed to "clear" the inert you now list.

Joanne Edwards

EPA/OPPTS/OPP/RD/IRB

(703) 305-6736

edwards.joanne@epa.gov



August 26, 2003

U.S. Environmental Protection Agency
Office of Pesticide Programs (7504C)
Ariel Rios Building
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

Re: Authorization of Designated Agent

Gentlemen:

Please let this letter serve to affirm that as an authorized officer of Agriliance LLC, Alice Walker, Ph.D. of Alice Walker Consulting, 481 Country Club Drive, Senatobia, Mississippi 38668, is appointed agent for Agriliance, LLC and is authorized to represent Agriliance, LLC, before the U.S. Environmental Protection Agency in matters relating to registration of pesticide products in the USA.

If you should have any questions or need further confirmation of this assignment, please do not hesitate to contact me. This appointment will remain in effect until further notice.

Very sincerely yours,

Carl Moberg
Director of Proprietary Marketing

cc: Alice Walker

Post-It® Fax Note	7671	Date	7/20	# of pages	1
To: <i>Osman Edwards</i>		From: <i>Alice Walker</i>			
Off/Dept.		Co.			
Phone #		Phone #			
Fax #		Fax #			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 20, 2002

Van der Salm Bulbfarm, Inc.
35306 NW Toenjes Road
Woodland, WA 98674

Subject: Actellic (Still Registered; No Longer in Stock)
Your Application Dated January 17, 2002

Dear Mr. Van Noort,

Your application is being returned to you. You should contact the basic registrant for Actellic SE, which is Agrilience, LLC; PO Box 64089; St. Paul, MN 55164-0089. The product registration contact is Steven Rogosheske at (651) 451-5409. For your information, the EPA Reg. No. 68119-17 was transferred to EPA Reg. No. 1381-170 on October 1, 1999. I recommend you contact the basis registrant regarding any concerns you may have for this product.

If you have any questions, please contact me at (703) 305-6736, or electronically at edwards.joanne@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Joanne S. Edwards".

Joanne S. Edwards, Entomologist
Insecticide-Rodenticide Branch
Registration Division (7505C)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 12, 2001

Steven Rogosheske
Agrilience, LLC
PO Box 64089
St. Paul, MN 55164-0089

Subject: Actellic 5E Insecticide
EPA Reg. No. 1381-170
Submission date: October 4, 2001
Subject: Rewording Section on Use for Stored or Bagged or Bulk Seed

Dear Mr. Rogosheske,

The label referred to above, submitted in connection with the registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is not acceptable for the reasons provided below.

The draft labeling rewording section on use for stored or bagged or bulk seed (*e.g.*, planting of dyed treated seed) requires the following data to support its use:

1. Residue studies in which corn and [grain] sorghum grain treated at the maximum 1X rate are planted and residues of concern (*i.e.* pirimiphos-methyl and its des-ethyl metabolite) determined in corn forage/stover and in sorghum forage/stover. These studies are being required in lieu of similar radiolabeled studies, and should be considered as the first tier of data gathering. If significant residues are found in the forage and/or stover, additional data may be required for the oxygen analogs of the residues of concern, and the need for rotational crop studies (in conjunction with the seed treatment use) will be evaluated.
2. Comprehensive documentation that the statement "For use only on waste seed resulting from the screening and conditioning process which is not to be used for any purpose" is practical and enforceable.
3. Avian Reproduction Testing (bobwhite and mallard) under Guideline 72-4.

Until these data are satisfied the labeling must continue to specify "Intended for storage insect control only, not meant to be used as a seed treatment or for control of soil insects".

If you have questions, please contact me on (703) 305-6736 or electronically at edwards.joanne@epa.gov.

Sincerely,

A handwritten signature in cursive script, appearing to read "Joanne S. Edwards".

Joanne S. Edwards, Entomologist
Insecticide-Rodenticide Branch
Registration Division (7505C)



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

285865

Application for Pesticide - Section I

1. Company/Product Number 1381-170	2. EPA Product Manager Insecticide-Rodenticide	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Actellic 5E Insecticide	PM # 04	
5. Name and Address of Applicant (Include ZIP Code) Agriliance, LLC P.O. Box 64089 St. Paul, MN 55164-0089 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Rewording section on use for Stored bagged or bulk seed.

Section - III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 28 & 64 oz. 1 & 15 gallons		5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Label accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other Stick-on booklet			

Section - IV

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Steve Rogosheske		Title Manager, Product Registration	
		Telephone No. (Include Area Code) (651) 451-5409	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Manager, Product Registration	
5. Typed Name Steven E. Rogosheske		5. Date Oct. 4, 2001	



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
285865

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code) <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must submitted					
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product			
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name	Title	Telephone No. (Include Area Code)
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature	3. Title	
4. Typed Name	5. Date	

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

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SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
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5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

2285865

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code) <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
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Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
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4. Typed Name		5. Date
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)

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- 1-5. Self-explanatory.
6. EPA Use Only.

A



Agronomy Services

B

October 4, 2001

Insecticide-Rodenticide Branch
Registration Division (7505C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Ave. NW
Washington, D.C. 20460

Re: Actellic 5E Insecticide
EPA Reg. No. 1381-170

Dear Sir or Madam:

Enclosed is an application for amendment to the subject product. We are not adding any additional use patterns that require data, we are just rewording and rearranging the label to make more of a distinction between use on grain for storage and use on stored bulk or bagged seed. We have also been asked by our seed company customers to add to the label a treatment for their seed screenings and waste seed that are awaiting removal from the site and eventual destruction. This temporarily stored waste is a harborage for insect pest infestations that the companies are trying to keep out of the facilities. This use involves no tolerance since the waste seed is not used, but destroyed as is stated on the label.

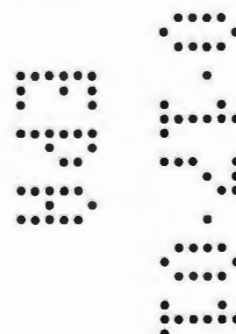
Enclosed in support of this registration is the application form (8570-1) and five copies of the proposed labeling with changes highlighted for ease of review.

If there are any questions, please contact me at the number below or by my FAX, (651) 451-4561.

Sincerely,

A handwritten signature in black ink, reading 'Steve Rogosheske'.

Steve Rogosheske
Manager, Product Registration
(651) 451-5409



Enclosures



ACTELIC[®] 5E INSECTICIDE

FOR CONTROL OF INSECTS ON STORED CORN AND GRAIN SORGHUM
(Including Bulk or Bagged Seed)

ACTIVE INGREDIENT:

Pirimiphos-methyl

0-(2-(diethylamino)-6-methyl-4-pyrimidinyl)0,0-dimethyl phosphorothioate 57%

INERT INGREDIENTS: 43%

TOTAL 100%

ACTELIC 5E INSECTICIDE contains 5 pounds active ingredient per gallon.

KEEP OUT OF REACH OF CHILDREN WARNING

FIRST AID

If in eyes

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

If swallowed

- Call a poison control center or doctor for treatment advice.
- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor.

If on skin or clothing

- Do not give anything by mouth to an unconscious person.
- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If inhaled

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. **NOTE TO PHYSICIAN:** Inducing vomiting as first aid for this substance may result in increased risk of chemical pneumonia or pulmonary edema caused by aspiration of the hydrocarbon solvent. Vomiting should be induced only under professional supervision. Atropine is antidotal for cholinesterase inhibition. Give 2 mg. of atropine intramuscularly or subcutaneously and repeat if symptoms of poisoning reappear. Pralidoxime (2 PAM) may be given if available. Give 1 gram intramuscularly or intravenously and repeat as necessary.

See side panel for additional precautionary statements.

EPA Reg. No. 1381-170

EPA Est No. _____

Agrilience, LLC
P.O. Box 64089
St. Paul, MN 55164-0089

Net Contents
_____ Gals.
0/F19/1

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING**

Causes eye irritation. Do not get in eyes. Wear goggles or face shield when handling.

Harmful if swallowed, inhaled, or absorbed through the skin. Avoid breathing vapors or spray mist. Keep container closed. Wear rubber gloves when handling concentrate.

Causes skin irritation. Do not get on skin or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal zones below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of waste.

In case of a significant spill, call CHEMTREC (800) 424-9300.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

PROHIBITIONS: Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

STORAGE: Store in a cool place and protect from freezing. If accidentally frozen, reconstitute by gently warming to room temperature and thoroughly mixing contents. Keep container closed when not in use.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL:

Metal Containers: Triple rinse(or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, by other procedures approved by State and local authorities.

Plastic Containers: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

INSECTS CONTROLLED WITH ACTELIC 5E INSECTICIDE

COLEOPTERA

LEPIDOPTERA

Cigarette beetle
Confused flour beetle
Corn sap beetle
Flat grain beetle
Granary weevil
Hairy fungus beetle

Maize weevil
Merchant grain beetle
Red flour beetle
Rice weevil
Sawtoothed beetle

Almond moth
Angoumois grain moth
Indian meal moth

GENERAL REMARKS AND PRECAUTIONS

- Grains treated with Actellic 5E Insecticide at rates indicated on this label may be used immediately for any food or feed purpose.
- Do not store diluted Actellic 5E Insecticide in spray tank more than 48 hours before use.
- Calibrate spray equipment and periodically check in order to ensure proper spray rates.
- Calibrate spray equipment and periodically check in order to ensure proper spray rates.
- Avoid severely dusty application sites.
- Intended for storage insect control only. Not meant to be used for control of soil insects.

APPLICATION DIRECTIONS FOR GRAIN STORAGE

ADMIXTURE OR TOP DRESSING

(Only ONE application method may be used per load of stored corn, popcorn or sorghum grain)

The best practice to protect stored corn and grain sorghum from insect infestation is to use an admixture treatment of ACTELLIC 5E INSECTICIDE. However, as it may not always be possible to move grain, a surface treatment of ACTELLIC 5E INSECTICIDE will help control light existing infestation and prevent the establishment of migrating insects. The top dressing application will not substitute for a treatment of the entire amount of stored corn or grain sorghum. But within your current stored grain management system, it will help protect the surface from invasion by insects. If grain is already heavily infested prior to going into storage, fumigation should be used.

Notice: Either treatment should only be used if the corn or grain sorghum has not previously received an application of ACTELLIC 5E INSECTICIDE. To determine whether the crop has been previously treated call toll-free 1-800-677-6324 for a free analysis.

ADMIXTURE TREATMENT

Apply spray solution uniformly with suitable application equipment as grain enters storage or export containers. Select nozzle size and operating pressure to adjust the application rate with flow of grain. Prepare desired dilution of ACTELLIC 5E INSECTICIDE in spray tank and mix well. Make sure spray solution stays mixed, especially in large holding tanks. Apply the spray solution as a coarse, uniform low pressure spray in order to minimize drift. Shield nozzle if necessary. Apply the specified amount of Actellic 5E Insecticide in 5 gallons of water or 3-5 gallons of at least twice refined soybean oil to each 30 tons (60,000 pounds) of grain according to the following rates.

	Fluid Ounces	ppm Concentration
Shelled Corn (field corn, seed corn, popcorn)	9.2-12.3	6-8
Grain Sorghum	9.2-12.3	6-8
Grain	No. of Bushels Approximately Equal to 30 Tons of Grain	
Shelled Corn (field corn, seed corn, popcorn)	1,071	
Grain Sorghum	1,071	

TOP DRESSING TREATMENT

To each 1,000 square feet of grain surface, apply 3 fluid ounces of Actellic 5E Insecticide diluted in 2 gallons of water. The treatment should be split as follows: Spray half of the mixture evenly over the surface and rake into the grain to a depth of 4 inches. Apply the remaining half of the mixture to the raked surface.

Before making a surface application of Actellic 5E Insecticide, it will be necessary to remove any webbing and break up crusting that exists on the grain surface. If high numbers of Indian Meal Moth worms (2-3 per sq ft) exist, it will be best to remove the webbing, fumigate, and then apply ACTELLIC 5E INSECTICIDE as a surface application. Mix the following amount of Actellic 5E Insecticide with 2 gallons of water for a total mixture to treat 1,000 sq ft of grain surface:

	Fluid Ounces	ppm Concentration
Corn and Sorghum	3.0	8

APPLICATION DIRECTIONS FOR STORED BULK OR BAGGED SEED* (Corn, Popcorn & Sorghum)

***Commercial Use Only on Seed conditioned, dyed and sold only for the purpose of planting.**

ADMIXTURE TREATMENT

Apply spray solution uniformly with suitable application equipment as grain enters storage or final treatment. Select nozzle size and operating pressure to adjust the application rate with flow of grain. Prepare desired dilution of Actellic 5E Insecticide in spray tank and mix well. Make sure spray solution stays mixed, especially in large holding tanks. Apply the spray solution as a coarse, uniform low-pressure spray in enclosed systems only. Apply the specified amount of Actellic 5E Insecticide in 5 gallons of water or 3-5 gallons of at least twice refined soybean oil to each 30 tons (60,000 pounds) of grain according to the following rates.

	Fluid Ounces	ppm Concentration
Shelled Corn (field corn, seed corn, popcorn)	9.2-12.3	6-8
Grain Sorghum	9.2-12.3	6-8
Grain	No. of Bushels Approximately Equal to 30 Tons of Grain	
Shelled Corn (field corn, seed corn, popcorn)	1,071	
Grain Sorghum	1,071	

TOP DRESSING TREATMENT FOR DISCARDED SCREENINGS AND UNUSEABLE SEED

To prevent insect refuge areas, treat screenings and waste seed stored and awaiting destruction with 3 fluid ounces of ACTELIC 5EC INSECTICIDE diluted in 2 gallons of water for every 1,000 square feet of surface area. The treatment should be split as follows: Spray half of the mixture evenly over the surface using a coarse spray and rake into the discarded waste seed to a depth of 4 inches. Apply the remaining half of the mixture to the raked surface.

Note: For use only on waste seed resulting from the screening and conditioning process which is not to be used for any purpose.

Notice of Warranty

Seller warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use. SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, NOR IS ANY REPRESENTATIVE OF SELLER AUTHORIZED TO MAKE ANY SUCH WARRANTY OR MODIFY THESE TERMS. This warranty does not extend to the storage, handling or use of this product contrary to label instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to Seller, and Buyer assumes the risk of any such storage, handling or use. Seller shall not be responsible for incidental or consequential damages, if any, resulting from a breach of warranty.

Actellic® is a registered trademark of Syngenta.



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FOR CONTROL OF INSECTS ON STORED CORN AND GRAIN SORGHUM
(Including Bulk or Bagged Seed)

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Pirimiphos-methyl

0-(2-(diethylamino)-6-methyl-4-pyrimidinyl)0,0-dimethyl phosphorothioate57%

INERT INGREDIENTS:43%

TOTAL.....100%

ACTELIC 5E INSECTICIDE contains 5 pounds active ingredient per gallon.

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- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

If swallowed

- Call a poison control center or doctor for treatment advice.
- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor.

If on skin or clothing

- Do not give anything by mouth to an unconscious person.
- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If inhaled

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. **NOTE TO PHYSICIAN:** Inducing vomiting as first aid for this substance may result in increased risk of chemical pneumonia or pulmonary edema caused by aspiration of the hydrocarbon solvent. Vomiting should be induced only under professional supervision. Atropine is antidotal for cholinesterase inhibition. Give 2 mg. of atropine intramuscularly or subcutaneously and repeat if symptoms of poisoning reappear. Pralidoxime (2 PAM) may be given if available. Give 1 gram intramuscularly or intravenously and repeat as necessary.

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EPA Reg. No. 1381-170

EPA Est No. _____

Agrilience, LLC
P.O. Box 64089
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Net Contents
_____ Gals.
0/F19/1

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Causes skin irritation. Do not get on skin or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal zones below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of waste.

In case of a significant spill, call CHEMTREC (800) 424-9300.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

PROHIBITIONS: Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

STORAGE: Store in a cool place and protect from freezing. If accidentally frozen, reconstitute by gently warming to room temperature and thoroughly mixing contents. Keep container closed when not in use.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL:

Metal Containers: Triple rinse(or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, by other procedures approved by State and local authorities.

Plastic Containers: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

INSECTS CONTROLLED WITH ACTELIC 5E INSECTICIDE

COLEOPTERA

Cigarette beetle
Confused flour beetle
Corn sap beetle
Flat grain beetle
Granary weevil
Hairy fungus beetle

Maize weevil
Merchant grain beetle
Red flour beetle
Rice weevil
Sawtoothed beetle

LEPIDOPTERA

Almond moth
Angoumois grain moth
Indian meal moth

GENERAL REMARKS AND PRECAUTIONS

- Grains treated with Actellic 5E Insecticide at rates indicated on this label may be used immediately for any food or feed purpose.
- Do not store diluted Actellic 5E Insecticide in spray tank more than 48 hours before use.
- Calibrate spray equipment and periodically check in order to ensure proper spray rates.
- Calibrate spray equipment and periodically check in order to ensure proper spray rates.
- Avoid severely dusty application sites.
- Intended for storage insect control only. Not meant to be used for control of soil insects.

APPLICATION DIRECTIONS FOR GRAIN STORAGE

ADMIXTURE OR TOP DRESSING

(Only ONE application method may be used per load of stored corn, popcorn or sorghum grain)

The best practice to protect stored corn and grain sorghum from insect infestation is to use an admixture treatment of ACTELIC 5E INSECTICIDE. However, as it may not always be possible to move grain, a surface treatment of ACTELIC 5E INSECTICIDE will help control light existing infestation and prevent the establishment of migrating insects. The top dressing application will not substitute for a treatment of the entire amount of stored corn or grain sorghum. But within your current stored grain management system, it will help protect the surface from invasion by insects. If grain is already heavily infested prior to going into storage, fumigation should be used.

Notice: Either treatment should only be used if the corn or grain sorghum has not previously received an application of ACTELIC 5E INSECTICIDE. To determine whether the crop has been previously treated call toll-free 1-800-677-6324 for a free analysis.

ADMIXTURE TREATMENT

Apply spray solution uniformly with suitable application equipment as grain enters storage or export containers. Select nozzle size and operating pressure to adjust the application rate with flow of grain. Prepare desired dilution of ACTELIC 5E INSECTICIDE in spray tank and mix well. Make sure spray solution stays mixed, especially in large holding tanks. Apply the spray solution as a coarse, uniform low pressure spray in order to minimize drift. Shield nozzle if necessary. Apply the specified amount of Actellic 5E Insecticide in 5 gallons of water or 3-5 gallons of at least twice refined soybean oil to each 30 tons (60,000 pounds) of grain according to the following rates.

	Fluid Ounces	ppm Concentration
Shelled Corn (field corn, seed corn, popcorn)	9.2-12.3	6-8
Grain Sorghum	9.2-12.3	6-8
Grain	No. of Bushels Approximately Equal to 30 Tons of Grain	
Shelled Corn (field corn, seed corn, popcorn)	1,071	
Grain Sorghum	1,071	

TOP DRESSING TREATMENT

To each 1,000 square feet of grain surface, apply 3 fluid ounces of Actellic 5E Insecticide diluted in 2 gallons of water. The treatment should be split as follows: Spray half of the mixture evenly over the surface and rake into the grain to a depth of 4 inches. Apply the remaining half of the mixture to the raked surface.

Before making a surface application of Actellic 5E Insecticide, it will be necessary to remove any webbing and break up crusting that exists on the grain surface. If high numbers of Indian Meal Moth worms (2-3 per sq ft) exist, it will be best to remove the webbing, fumigate, and then apply ACTELIC 5E INSECTICIDE as a surface application. Mix the following amount of Actellic 5E Insecticide with 2 gallons of water for a total mixture to treat 1,000 sq ft of grain surface:

	Fluid Ounces	ppm Concentration
Corn and Sorghum	3.0	8

APPLICATION DIRECTIONS FOR STORED BULK OR BAGGED SEED* (Corn, Popcorn & Sorghum)

***Commercial Use Only on Seed conditioned, dyed and sold only for the purpose of planting.**

ADMIXTURE TREATMENT

Apply spray solution uniformly with suitable application equipment as grain enters storage or final treatment. Select nozzle size and operating pressure to adjust the application rate with flow of grain. Prepare desired dilution of Actellic 5E Insecticide in spray tank and mix well. Make sure spray solution stays mixed, especially in large holding tanks. Apply the spray solution as a coarse, uniform low-pressure spray in enclosed systems only. Apply the specified amount of Actellic 5E Insecticide in 5 gallons of water or 3-5 gallons of at least twice refined soybean oil to each 30 tons (60,000 pounds) of grain according to the following rates.

	Fluid Ounces	ppm Concentration
Shelled Corn (field corn, seed corn, popcorn)	9.2-12.3	6-8
Grain Sorghum	9.2-12.3	6-8
Grain	No. of Bushels Approximately Equal to 30 Tons of Grain	
Shelled Corn (field corn, seed corn, popcorn)	1,071	
Grain Sorghum	1,071	

TOP DRESSING TREATMENT FOR DISCARDED SCREENINGS AND UNUSEABLE SEED

To prevent insect refuge areas, treat screenings and waste seed stored and awaiting destruction with 3 fluid ounces of ACTELIC 5EC INSECTICIDE diluted in 2 gallons of water for every 1,000 square feet of surface area. The treatment should be split as follows: Spray half of the mixture evenly over the surface using a coarse spray and rake into the discarded waste seed to a depth of 4 inches. Apply the remaining half of the mixture to the raked surface.

Note: For use only on waste seed resulting from the screening and conditioning process which is not to be used for any purpose.

Notice of Warranty

Seller warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use. SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, NOR IS ANY REPRESENTATIVE OF SELLER AUTHORIZED TO MAKE ANY SUCH WARRANTY OR MODIFY THESE TERMS. This warranty does not extend to the storage, handling or use of this product contrary to label instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to Seller, and Buyer assumes the risk of any such storage, handling or use. Seller shall not be responsible for incidental or consequential damages, if any, resulting from a breach of warranty.

Actellic® is a registered trademark of Syngenta.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

10/19/2001

STEVE ROGOSHESKE
AGRILIANCE, LLC
P.O. BOX 64089
ST. PAUL MN 551640089

OFFICE OF
PREVENTION PESTICIDES AND
TOXIC SUBSTANCES

PRODUCT NAME: ACTELIC 5E INSECTICIDE
COMPANY NAME: AGRILIANCE, LLC
OPP IDENTIFICATION NUMBER: 285865
EPA REGISTRATION NUMBER: 1381-170
EPA RECEIPT DATE: 10/17/2001

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Insect/Rodent Br., Product Manager 04, at (703) 305-5404.

Sincerely,

A handwritten signature in cursive script, appearing to read "J. White", is positioned below the "Sincerely," text.

Front End Processing Staff
Information Services Branch
Program Management and Support Division



ACTELIC[®] 5E INSECTICIDE

FOR CONTROL OF INSECTS ON STORED CORN AND GRAIN SORGHUM
(Including Bulk or Bagged Seed)

ACTIVE INGREDIENT:

Pirimiphos-methyl

0-(2-(diethylamino)-6-methyl-4-pyrimidinyl)0,0-dimethyl phosphorothioate57%

INERT INGREDIENTS:43%

TOTAL.....100%

ACTELIC 5E INSECTICIDE contains 5 pounds active ingredient per gallon.

KEEP OUT OF REACH OF CHILDREN WARNING

FIRST AID

- | | |
|-------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| If in eyes | <ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. |
| If swallowed | <ul style="list-style-type: none">• Call a poison control center or doctor for treatment advice.• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor. |
| If on skin or clothing | <ul style="list-style-type: none">• Do not give anything by mouth to an unconscious person.• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice. |
| If inhaled | <ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice. |

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. **NOTE TO PHYSICIAN:** Inducing vomiting as first aid for this substance may result in increased risk of chemical pneumonia or pulmonary edema caused by aspiration of the hydrocarbon solvent. Vomiting should be induced only under professional supervision. Atropine is antidotal for cholinesterase inhibition. Give 2 mg. of atropine intramuscularly or subcutaneously and repeat if symptoms of poisoning reappear. Pralidoxime (2 PAM) may be given if available. Give 1 gram intramuscularly or intravenously and repeat as necessary.

See side panel for additional precautionary statements.

EPA Reg. No. 1381-170

EPA Est No. _____

Agrilience, LLC
P.O. Box 64089
St. Paul, MN 55164-0089

Net Contents
_____ Gals.
0/F19/1

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING**

Causes eye irritation. Do not get in eyes. Wear goggles or face shield when handling.

Harmful if swallowed, inhaled, or absorbed through the skin. Avoid breathing vapors or spray mist. Keep container closed. Wear rubber gloves when handling concentrate.

Causes skin irritation. Do not get on skin or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal zones below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of waste.

In case of a significant spill, call CHEMTREC (800) 424-9300.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

PROHIBITIONS: Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

STORAGE: Store in a cool place and protect from freezing. If accidentally frozen, reconstitute by gently warming to room temperature and thoroughly mixing contents. Keep container closed when not in use.

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DIRECTIONS FOR USE

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INSECTS CONTROLLED WITH ACTELIC 5E INSECTICIDE

COLEOPTERA		LEPIDOPTERA
Cigarette beetle	Maize weevil	Almond moth
Confused flour beetle	Merchant grain beetle	Angoumois grain moth
Corn sap beetle	Red flour beetle	Indian meal moth
Flat grain beetle	Rice weevil	
Granary weevil	Sawtoothed beetle	
Hairy fungus beetle		

GENERAL REMARKS AND PRECAUTIONS

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ADMIXTURE OR TOP DRESSING

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Corn and Sorghum	3.0	8

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Note: For use only on waste seed resulting from the screening and conditioning process which is not to be used for any purpose.

Notice of Warranty

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Actellic® is a registered trademark of Syngenta.

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United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
401 M Street SW
Washington, DC 20460

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationary, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product

6836-70 3

Distributor Company Number

58880 6

Note: Do not submit distributor product labels

Name of Registered Product (basic product name accepted by EPA)

Bardac 205M-7.5

Distributor Product Name

Sanicep 600

Name and Address of Distributor (Type; include ZIP code)

Mr. Wally Drost, Jr.
PDQ Manufacturing, Inc.
71 Merk Davis Street
Ellijay, GA 30540

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...", "distributed by..."; or sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor

Wally Drost, Jr.

General Manager

Date

3/28/00

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant

Celeste Rame

Regulatory Services
Lonza Inc.

Date

7/26/2000 108 7/7/00



United States Environmental Protection Agency
Office of Pesticide Programs (25505C)

Washington, DC 20460

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This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product

6836-70 5

Distributor Company Number

12035

Note: Do not submit distributor product labels

Name of Registered Product (basic product name accepted by EPA)

Bardac 205m-7.5

Distributor Product Name

Food Industry Quaternary Disinfectant

Name and Address of Distributor (Type; include ZIP code)

Century Labs, Inc.
3200 S. 24th Street
Shawnee Mission, KS 66201

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
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Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor

Larry A. Borcharding General Manager

Date

9/19/94

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant

John P. Paydera

Manager,
Regulatory Services

Date

OCT 17 1994

Storage Stability of
ACTELLIC 5E GFU336A

Reference Number	Container	Length of Storage	Conditions	Analysis of AI Content
191/2	-	initial analysis	-	60.68%
191/2-3	conolene*	14 mos.	ambient	60.76%
191/2-6	conolene*	10 mos.	cycling**	60.06%

*Fluorine-treated, high-density polypropylene
**20°-37°C.

191/2-3
191/2-6
191/2-3
191/2-6
191/2-3
191/2-6

